REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for chlormequat in pears, cereals and commodities of animal origin[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom (hereafter - evaluating Member State UK (EMS UK)), received an application from the company BASF to modify the existing MRLs for chlormequat in cereals and several commodities of animal origin. The EMS UK proposed to raise MRLs in rye and oat grain and several animal commodities to accommodate the NEU use of chlormequat on cereals. The Netherlands (EMS NL) received an application from Nederlandse Fruittelers Organisatie to maintain the temporary MRL of 0.1 mg/kg for chlormequat in pears until 31 July 2017, in order to accommodate for carry-over of chlormequat residues due to formerly authorized uses on pear trees. The targeted monitoring data provide evidence that, in general, chlormequat residues in pears produced in the Netherlands and Belgium are declining. In 2013 and onwards, 95 % of the samples of pears produced in the Netherlands and Belgium in areas where chlormequat was used in pear orchards before 2003 will contain residues at or below the level of 0.1 mg/kg. The submitted residue trials on cereals indicate that a higher MRL is required for oat and rye grain to support the intended NEU use. The new use on cereals results in a need to raise the existing MRLs for chlormequat in ruminant muscle, liver, kidney, swine kidney and milk. Based on the risk assessment results, EFSA concludes that the temporary MRL for pears and the intended use of chlormequat on rye and oats and the subsequent residues in animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

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KEY WORDS

chlormequat, pears, rye and oat grain, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, quaternary ammonium plant growth regulator

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State United Kingdom (EMS UK), received an application from the company BASF to modify the existing MRLs for chlormequat in various cereals and animal commodities in order to accommodate the intended use of chlormequat on cereals in the UK. The Netherlands (EMS NL), received an application from Nederlandse Fruittelers Organisatie (NFO) to maintain the current temporary MRL of 0.1 mg/kg for chlormequat in pears until 31 July 2017 in order to accommodate for the carry-over of chlormequat residues due to formerly authorized uses on pear trees. Both EMSs drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA on 1 July 2013.

Since both applications refer to the modification of the MRLs for chlormequat, for reasons of efficiency EFSA assessed both applications in one reasoned opinion.

EFSA bases its assessment on the evaluation report submitted by the Evaluating Member States Netherlands and United Kingdom, the Draft Assessment Report (DAR) prepared by the rapporteur Member State (RMS) United Kingdom under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance chlormequat, as well as the conclusions from a previous EFSA reasoned opinion on chlormequat.

The toxicological profile of chlormequat was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.04 mg/kg bw per day and an ARfD of 0.09 mg/kg bw for chlormequat chloride.

The metabolism of chlormequat chloride in primary crops was investigated in cereals only, for which the peer review concluded to establish the residue definition for enforcement and risk assessment as the “sum of chlormequat and its salts, expressed as chlormequat chloride”. No metabolism studies are available for chlormequat in fruits. Considering that the existing temporary MRL in pears is set for chlormequat, it is proposed to define the relevant residue in pears as chlormequat under the current MRL application. For the intended uses on cereals EFSA concludes that the metabolism of chlormequat is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable. The enforcement residue definition according to Regulation (EC) No 396/2005 is set as chlormequat (cation).

The EMS NL submitted targeted (1998-2012) and non-targeted (2010-2012) monitoring data from the Netherlands and Belgium on residue levels of chlormequat (cation) in pears. The non-targeted monitoring data give an indication that for pears harvested in 2013 and onwards, the 95th percentile of residues will be below the LOQ of 0.05 mg/kg. Thus, based on a non-targeted monitoring data, the setting of temporary MRL for chlormequat in pears is no longer necessary. The targeted monitoring data (2004-2012), however, indicate that for the future years, the 95th percentile of chlormequat residues in pears will be below the MRL of 0.1 mg/kg, but still above the LOQ of 0.05 mg/kg.

The submitted supervised residue field trials on cereals indicate that in order to accommodate the intended NEU use, a higher MRL of 4 mg/kg in rye grain and 15 mg/kg in oats grain would be required for chlormequat chloride corresponding to 3 mg/kg and 9 mg/kg, respectively, for chlormequat (cation). Adequate analytical enforcement methods are available to control chlormequat residues in the crops under consideration.

The effect of processing on the nature of chlormequat chloride was investigated in studies simulating beer brewing and bread making and under these conditions no degradation of chlormequat was observed. EFSA concludes that in processed cereals chlormequat will be the main residue of concern. In order to derive a general residue definition for processed commodities, additional studies investigating the nature of chlormequat under sterilisation and pasteurization conditions would be required. New studies to assess the magnitude of chlormequat residues during the processing of the

crops under consideration have not been submitted in the framework of the current application. Such studies with cereals have been assessed in the framework of the peer review.

The occurrence of chlormequat chloride in rotational crops was investigated under the peer review, which concluded that residues of chlormequat may be of concern when cereals are planted as rotational crops but noted that residues in rotated cereals should not be higher than in cereals directly treated with chlormequat chloride according to the notified uses. Thus, in order to avoid residues of chlormequat in cereals when planted as rotational crops, the Member States, when granting authorisations of chlormequat shall apply the necessary risk mitigation measures.

Cereals and their by products can be fed to livestock and therefore the potential carry-over of chlormequat residues into food of animal origin was assessed. The calculated livestock dietary burdens exceed the trigger value of 0.1 mg/kg (dry matter) for all relevant livestock species and are driven by uses on barley and oats. The peer review concluded that, generally, the metabolism in ruminants and non-ruminants proceeds in a similar pathway and that the residue definition for the risk assessment and enforcement in livestock is set as the "sum of chlormequat and its salts, expressed as chlormequat chloride". The livestock feeding studies were used to estimate the carry-over of chlormequat chloride residues into food of animal origin at the calculated dietary burdens. The results of the feeding studies indicate that at the calculated livestock dietary burdens the existing MRLs for chlormequat (cation) have to be raised for ruminant meat, liver and kidney, swine kidney and milk. An adequate analytical enforcement method is available to control chlormequat residues in food of animal origin.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The existing MRLs are set for chlormequat (cation) and therefore the risk assessment values which were available for chlormequat chloride were expressed as chlormequat (cation), by applying the molecular weight conversion factor. For the calculation of chronic exposure, EFSA used the median residue values for cereals as derived from the submitted residue trials. For pears the mean value derived from non-targeted monitoring data of 2012 was used as an input value. For commodities of animal origin the risk assessment values were used as input values. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for chlormequat.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 27 % of the ADI (WHO Cluster diet E). The individual contribution of residues in the crops under consideration to the total consumer exposure (in percentage of the ADI) accounted for 10 % for wheat (WHO Cluster diet B), 6 % for rye and 3 % for oat (DK child diet), 1.5 % for barley (IE adult diet) and 0.04 % for pears (DK child diet). The contribution of chlormequat residues in milk accounted for 3 % of the ADI and was individually below 0.2 % of the ADI other animal commodities under consideration.

No acute consumer risk was identified in relation to the MRL proposal for pears and for the intended use on rye and oat grain and resulting residues in commodities of animal origin. The calculated maximum exposure in percentage of the ARfD was 14 % for oats, 13 % for pears, 8 % for wheat, and below 5 % other commodities under consideration.

EFSA concludes that the temporary MRL for pears and the intended use of chlormequat on rye and oats and the subsequent residues in animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Chlormequat[b]				
0130020	Pears	0.1 (until 31 July 2014)	0.1	The submitted residue data indicate that in general the residues in pears produced in the Netherlands and Belgium are declining. In 2013 and onwards 95 % of the samples of pears produced in the Netherlands and Belgium in areas where chlormequat was used in pear orchards in the past (before 2003) will contain residues at or below the level of 0.1 mg/kg. Risk managers to decide if and for how long the current temporary MRL should be maintained. The corresponding MRL proposal for chlormequat chloride is 0.15 mg/kg.
0500010	Barley	2	No change	The submitted residue data indicate that a lower MRL of 1.5 mg/kg for chlormequat would be sufficient. The lowering, however, is not proposed since more critical uses of chlormequat on cereals might exist, requiring the existing MRL. The corresponding MRL proposal for chlormequat chloride is 2 mg/kg.
0500050	Oats	5	9	The MRL proposals are sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 15 mg/kg in oats and 4 mg/kg in rye.
0500070	Rye	2	3	
0500090	Wheat	2	No change	The submitted residue data indicate that a lower MRL of 1.5 mg/kg would be sufficient. The lowering, however, is not proposed since more critical uses of chlormequat on cereals might exist, requiring the existing MRL. The corresponding MRL proposal for chlormequat chloride is 2 mg/kg.
1011040	Swine kidney	0.05*	0.12	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.15 mg/kg.
1012010 1013010 1014010 1015010 1017010	Ruminant muscle	0.05*	0.08	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.1 mg/kg.
1012020 1013020 1014020 1015020 1017020	Ruminant fat	0.05*	No change	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.05 mg/kg.
1012030 1013030 1014030 1015030 1017030	Ruminant liver	0.1*	0.12	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.15 mg/kg.

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Chlormequat[b]				
1012040 1013040 1014040 1015040 1017040	Ruminant kidney	0.2*	0.4	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.5 mg/kg.
2030000	Milk	0.05*	0.06	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.07 mg/kg.

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): Residue calculated as cation
(*): Indicates that the MRL is set at the limit of analytical quantification.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 6
Background 7
Terms of reference 8
The active substance and its use pattern 9
Assessment 11
1. Method of analysis 11
1.1. Methods for enforcement of residues in food of plant origin 11
1.2. Methods for enforcement of residues in food of animal origin 11
2. Mammalian toxicology 12
3. Residues 12
3.1. Nature and magnitude of residues in plant 12
3.1.1. Primary crops 12
3.1.2. Rotational crops 22
3.2. Nature and magnitude of residues in livestock 24
3.2.1. Dietary burden of livestock 24
3.2.2. Nature of residues 25
3.2.3. Magnitude of residues 26
4. Consumer risk assessment 30
Conclusions and recommendations 32
References 35
Appendices 37
Appendix A. Good Agricultural Practice (GAPs) 37
Appendix B. Pesticide Residue Intake Model (PRIMo) 38
Appendix C. Existing EU maximum residue levels (MRLs) 40
Appendix D. Results of official controls of the Netherlands of the years 2010, 2011 and 2012 43
Appendix E. Official controls of Belgium of 2010, 201 and 2012 45
Appendix F. Control results from the Dutch Fruit growers association 52
Appendix G. Control results from Belgium growers organisation (Verbond van Belgische Tuinbouwcoöperaties (VBT)) 55
Abbreviations 56

BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

The United Kingdom, hereafter referred to as the evaluating Member State United Kingdom (EMS UK), received an application from the company BASF[6] to modify the existing MRLs for the active substance chlormequat in rye, oats and several animal commodities. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 1 July 2013. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00625 and the following subject:

Chlormequat chloride - Application to modify the existing MRLs in various commodities.

The EMS UK proposed to raise the existing MRLs for chlormequat in oat grain (to 15 mg/kg), rye grain (4 mg/kg) and in ruminant meat (0.1* mg/kg), fat (0.1* mg/kg), liver (0.2 mg/kg) and kidney (0.5 mg/kg), in swine and poultry liver (0.1 mg/kg), kidney and edible offal (0.2 mg/kg (swine) and 0.1 mg/kg (poultry)), and in milk (0.15 mg/kg).

The Netherlands, hereafter referred to as the evaluating Member State Netherlands (EMS NL), received an application from the company Nederlandse Fruittelers Organisatie (NFO)[7] to maintain the current temporary MRL for the active substance chlormequat in pears until 31 July 2017. This application was notified to the European Commission and EFSA and was subsequently evaluated in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 1 July 2013. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00622 and the following subject:

Chlormequat - Application to set new MRLs in pears.

The EMS NL proposed to extend the validity of the existing temporary MRL of 0.1 mg/kg for chlormequat in pears for another three years period until 31 July 2017.

EFSA proceeded with the assessment of the applications and evaluation reports as required by Article 10 of the Regulation. Since both MRL applications refer to the active substance chlormequat, for the reasons of efficiency EFSA combined the assessment in one reasoned opinion.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[6] BASF, Earl Road, O. Box 4, SK8 6QG, Cheadle Hulme, The United Kingdom.

[7] Nederlandse Fruittelers Organisatie (NFO), P.O. Box 344, 2700 AH, Zoetermeer, The Netherlands.

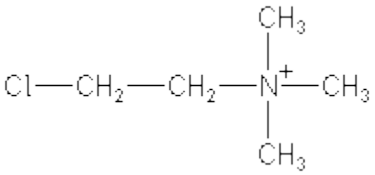
TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided. In this particular case the deadline for providing reasoned opinions is 1 October 2013.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Chlormequat is the ISO common name for 2-chloroethyltrimethylammonium (IUPAC).



Molecular weight: 122.61

Chlormequat belongs to the class of quaternary ammonium compounds. It is usually applied as a chloride salt (2-chloroethyltrimethylammonium chloride). Chlormequat acts as a plant growth regulator by inhibiting cell elongation, which results in a sturdier plant by shortening and strengthening the stem. It may also be used to increase the flowering and/or fruit setting. It mainly acts by inhibiting the gibberellin biosynthesis.

Chlormequat (as chloride variant) was evaluated in the framework of Directive 91/414/EEC with the United Kingdom being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process included a single foliar application on winter and spring wheat, winter and spring barley, triticale, durum wheat, spelt wheat, rye and oats from growth stage of BBCH 30 up to growth stage of BBCH 49, in all EU countries. The peer review has been finalized and an EFSA conclusion is available (EFSA, 2008). Chlormequat was included in Annex I of Directive 91/414/EEC by means of Commission Directive 2009/37/EC[8], which was modified by Commission Directive 2010/2/EU[9]. Chlormequat is thus considered approved according to the Regulation (EC) No 1107/2009 for use as a plant growth regulator on cereals and non-edible crops only.

The EU MRLs for chlormequat have been first set in 1996, which were revised in 2000 by Directive 2000/42/EC[10]; among other modifications the MRL for chlormequat in pears was lowered to the analytical limit of quantification of 0.05 mg/kg, because the use of chlormequat on pears was no longer authorized. However, it turned out that chlormequat residues were still found in pears, due to the persistence of the active substance in previously treated pear trees and therefore the MRL was raised again to 0.5 mg/kg in 2001 and since then successively lowered to the current MRL level of 0.1 mg/kg. In Appendix C all current EU MRLs for chlormequat (calculated as cation) as established in Annexes II and IIIB of Regulation (EC) No 396/2005 can be found. According to Commission Regulation (EC) No 822/2009[11], the existing MRL for pears is set at 0.1 mg/kg and shall apply until 31 July 2014. The existing MRLs for chlormequat in cereals are set at 2 mg/kg in barley, wheat and rye and at 5 mg/kg in oats. For animal commodities MRLs are set at the limit of quantification (LOQ): 0.1 mg/kg in liver, 0.2 mg/kg in bovine kidney and 0.05 mg/kg in other commodities.

The Codex Alimentarius Commission has established CXLs for chlormequat (calculated as cation) in a wide range of plant and animal commodities; for cereals a CXL of 2 mg/kg is set in barley, 10 mg/kg

[8] Commission Directive 2009/37/EC of 23 April 2009 amending Council Directive 91/414/EEC to include chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin as active substances OJ L 104, 24.4.2009, p. 23-32.

[9] Commission Directive 2010/2/EU of 27 January 2010 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance chlormequat. OJ L 24, 28.1.2010, p.11-13.

[10] Commission Directive 2000/42/EC of 22 June 2000 amending Annexes to Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC on the fixing of maximum levels for pesticide residues in and on cereals, foodstuffs of animal origin and certain products of plant origin, including fruit and vegetables respectively. OJ L 158, 30.6.2000, p.51-75

[11] Corrigendum to Commission Regulation (EC) No 822/2009 of 27 August 2009 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, atrazine, chlormequat, cyprodinil, dithiocarbamates, fludioxonil, fluroxypyr, indoxacarb, mandipropamid, potassium tri-iodide, spirotetramat, tetraconazole, and thiram in or on certain products. OJ L 60, 10.3.2010, p. 26-46.

in oats, 3 mg/kg in wheat and rye. The review of chlormequat MRLs according to Article 12 of Regulation (EC) No 396/2005 is currently at an early stage and is not expected to be finalized imminently.

According to the current legislation, the MRL of 0.1 mg/kg for chlormequat in pears will apply until 31 July 2014. The EMS Netherlands is however of the opinion that, based on the currently available monitoring data, residue levels of chlormequat in pears will still exceed the LOQ of 0.05 mg/kg after that date. In 2009 EFSA already issued a reasoned opinion, concluding that temporary MRL of 0.1 mg/kg might be required until 31 July 2014 to accommodate the carry over of chlormequat residues from pear tree resulting from the previous uses of chlormequat on pears (EFSA, 2009). Now the period for which the temporary MRL of 0.1 mg/kg is applicable is going to expire and therefore the EMS NL has submitted a new application to maintain the temporary MRL until 31 July 2017.

The EMS UK received an application for a new use of chlormequat chloride on cereals in the United Kingdom (see Appendix A).

ASSESSMENT

EFSA bases its assessment on the evaluation reports submitted by Evaluating Member States (Netherlands, 2013; United Kingdom, 2013), the Draft Assessment Report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC (United Kingdom, 2007; 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance chlormequat (EFSA, 2008) as well as the conclusions from the previous EFSA reasoned opinion on chlormequat (EFSA, 2009). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[12] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of chlormequat chloride residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (United Kingdom, 2007; EFSA, 2008). The peer review concluded that a HPLC-MS/MS method is sufficiently validated for the determination of chlormequat chloride residues in commodities with high water-, high oil- and high acid content at the LOQ of 0.05 mg/kg and in dry commodities at the LOQ of 0.5 mg/kg (EFSA, 2008). The LOQ for chlormequat (cation), recalculated using the molecular weight conversion factor[13] of 0.78, would be 0.039 mg/kg for high water-, high oil- and high acid content commodities and 0.39 mg/kg for dry commodities.

According to the data base of the EU Reference Laboratories for Residues of Pesticides, an HPLC-MS/MS method can quantify chlormequat (cation)in high water content and dry matrices and above at the validated LOQ of 0.01 mg/kg.

It is thus concluded that adequate analytical enforcement methods are available to control residues of chlormequat in cereals and pears.

1.2. Methods for enforcement of residues in food of animal origin

The analytical method for the determination of chlormequat chloride residues in commodities of animal origin was evaluated during the peer review under Directive 91/414/EEC (United Kingdom, 2007; EFSA, 2008). The provided analytical method was considered not acceptable and the applicant was required to demonstrate the extraction efficiency for the primary method and for the ILV method (EFSA, 2009). The submission of the monitoring method for the determination of chlormequat chloride in animal products was also noted as confirmatory data requirement in the Commission Directive 2010/2/EU.

In the framework of the current application, validation data for the analytical enforcement method and its ILV were submitted as required under the peer review for the determination of chlormequat chloride in animal matrices (United Kingdom, 2013). The determination of chlormequat chloride in animal matrices, eggs and milk was performed using HPLC-MS/MS. Data indicate that analytical method is sufficiently validated for the determination of chlormequat chloride residues in meat, kidney, milk, eggs and fat at the LOQ of 0.01 mg/kg and in liver at the LOQ of 0.05 mg/kg. The LOQ for chlormequat (cation), recalculated using the molecular weight conversion factor of 0.78, would be 0.0078 mg/kg for meat, kidney, milk, eggs and fat and 0.039 mg/kg for liver.

[12] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

[13] MW chlormequat chloride =158.1; MW chlormequat = 122.6

EFSA concludes that sufficiently validated analytical method is available to control residues of chlormequat in animal commodities.

2. Mammalian toxicology

The toxicological properties of chlormequat have been evaluated under Directive 91/414/EEC (EFSA, 2008) and reference values have been derived for chlormequat chloride. EFSA derived reference values are also for chlormequat (cation) based on the molecular weight of both compounds. The toxicological reference values are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Chlormequat chloride					
ADI	EFSA	2008	0.04 mg/kg bw per day	1 yr dog	100
ARfD	EFSA	2008	0.09 mg/kg bw	4 wk dog	100
Chlormequat (cation)					
ADI	-	-	0.031 mg/kg bw per day	1 yr dog	100
ARfD	-	-	0.07 mg/kg bw	4 wk dog	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of ^{14}C-chlormequat chloride in cereals was evaluated in the framework of the peer review under Directive 91/414/EEC (United Kingdom, 2007; EFSA, 2008). The details of the metabolism study are presented in the table below.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Application details				
		Method, F or G[(a)]	Rate	No/ Interval	Sampling	Remarks
Cereals	Spring wheat	Foliar/G	1.4 kg a.s./ha	1/78 days after sowing (BBCH 71)	0, 28 and 84 DAT- forage and 118 DALA- grain, straw	The application rate is expressed as chlormequat-chloride

(a): Outdoor/field application (F) or glasshouse/protected crops/indoor application (G)

Total radioactive residues (TRR) in forage samples decreased from 49.24 mg eq./kg at day 0 to 14.35 mg eq./kg at day 84 after application. 118 DAT the total radioactivity in straw and grain was 45.8 mg eq./kg and 1.3 mg eq./kg, respectively. Whereas the radioactive residues in forage and straw samples were mostly extractable (85-90 % TRR and 89 % TRR respectively), only 52 % TRR was extracted from grain samples. The un-extracted residues in straw and grain samples were further investigated. In grain 0.2 %, 35.6 %, 1.2 % and 15.8 % TRR were found in the protein, lignin, cellulose and starch fraction respectively. In straw 5.1 % and 0.1 % TRR were found in the lignin and

the cellulose fraction respectively. In extracts of forage sampled at day 0, 28 and 84 respectively, 40-42 mg/kg, 32-33 mg/kg and 9.7-10.5 mg/kg chlormequat were found.

Concentrations of 36-37 mg/kg (78-81 % of TRR) and 0.37-0.41 mg/kg (28-30 % of TRR) chlormequat were detected in straw and grain. Betain[14] was the only metabolite identified (0.04-0.05 mg/kg or 3-5 % of TRR in grain and 0.06 mg/kg or 0.1 % of TRR in straw) (EFSA, 2008).

The peer review concluded that the metabolism study is acceptable despite the fact that the growth stage for cereals in representative uses (BBCH 30-49) differs from the growth stage in the metabolism study (BBCH 71). The metabolism study demonstrated that chlormequat is the main compound identified in straw and grain. Oxidation to form minor amounts of betain has been shown in straw and grain. Betain is found in biochemical pathways of the body and is of no toxicological concern. Residues, incorporated mainly in the lignin fraction (for grain and straw) and the starch fraction (in grain), have been found.

Considering that the available analytical methods determine the chlormequat cation, the peer review concluded that the residue definition in plants for enforcement and risk assessment shall be set as the "sum of chlormequat and its salts, expressed as chlormequat chloride". The residue definition established in the Regulation (EC) No 396/2005 is set as "chlormequat" (calculated as cation).

No metabolism studies are available for chlormequat in fruits. The carry over of chlormequat residues was only observed for the unchanged parent compound and seems to be caused by the slow degradation and subsequent accumulation of parent chlormequat in the stem of the trees (EFSA, 2008). Considering that the existing temporary MRL in pears is set for chlormequat (cation) and the submitted monitoring data are reported for chlormequat (cation), it is proposed to define the relevant residue for pears as chlormequat (cation).

EFSA concludes that the metabolism of chlormequat in cereals is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Pears

Currently the use of chlormequat in pears is no longer authorised, but a temporary MRL of 0.1 mg/kg applies in order to accommodate for the carry over of chlormequat residues from uses formerly authorized in Belgium and the Netherlands. In order to substantiate the proposal for the extension of the temporary MRL, the EMS NL submitted monitoring data on residues of chlormequat in pears. Different sources of information were reported, providing targeted and non-targeted monitoring data on the levels of chlormequat residues (calculated as cation) in pears:

a) <u>non-targeted monitoring data for pears produced in Belgium and the Netherlands:</u>

- ✓ monitoring results for pears analysed by the Dutch Food and Consumer Product Safety Authority (NVWA) (2010: 8 samples from NL; 2011: 20 samples from NL and 1 sample from BE; 2012: 29 samples from NL) (Appendix D)
- ✓ monitoring results for pears originating from different countries analysed by the Belgian Food Inspection and Ministry of Agriculture (2010: 70 samples from BE, 16 samples origin not specified; 2011: 55 samples from BE, 2 samples from NL; 2012: 47 samples from BE) (Appendix E)
- ✓ In the framework of the previous assessment of the residue situation in pears official monitoring data from Belgium and the Netherlands were provided (EFSA, 2009) (2004: 51 samples, 2005: 27 samples, 2006: 109 samples, 2007: 54 samples)

[14] (trimethylammonio) acetate.

Pear samples originating from third countries as well as from other EU countries were excluded from the assessment.

The results of the non-targeted monitoring data are summarised in Table 3-2.

Table 3-2: Non-targeted monitoring data for chlormequat (calculated as cation)

Year of harvest	No of samples/origin of the samples	≤ 0.05 mg/kg	>0.05-0.1 mg/kg	>0.1 mg/kg	Mean residue (mg/kg)	Highest residue (mg/kg)	95th percentile (mg(kg)
2004[a)]	51 (NL + BE)	42	5	4	0.061	0.19	0.15
2005[a)]	27 (NL + BE)	19	6	2	0.061	0.14	0.12
2006[a)]	109 (NL + BE)	100	3	6	0.057	0.41	0.1
2007[a)]	54 (NL + BE)	49	4	1	0.052	0.13	0.065
2008	No residue data available						
2009	No residue data available						
2010	70 E+8 NL+16 n.n[d]	86	7	1	0.019	0.12	0.04
2011	56 BE+22 NL	75	3	0	0.014	0.098	0.04
2012	47 BE+29 NL	73	2	1	0.017	0.12	0.045

a) Data reported in EFSA, 2009.
b) Data where the origin of the sample was not specified were not excluded from the assessment.

b) <u>targeted monitoring data:</u>

- ✓ results of controls performed by Dutch Fruit Growers Association (1998 to 2012) (Appendix F);
- ✓ results of controls performed by the Belgian growers organisation (Verbond van Belgische Tuinbouwcoöperaties (VBT)) (2010, 2011 and 2012) (Appendix G).

The data from 1998 to 2003 were not included in the assessment since these data might reflect a situation where chlormequat was still used on pears. The results of the Dutch and Belgian targeted monitoring data for 2004 to 2012 are summarised in Table 3-3.

Table 3-3: Targeted monitoring data for chlormequat (calculated as cation)

Year of harvest	No of samples/origin of the samples	≤ 0.05 mg/kg	>0.05-0.1 mg/kg	>0.1 mg/kg	Mean residue (mg/kg)	Highest residue (mg/kg)	95th percentile (mg(kg)
2004	85 NL	66	13	6	0.039	0.24	0.11
2005	71 NL	51	15	5	0.044	0.27	0.12
2006	68 NL	53	7	8	0.041	0.22	0.157
2007	65 NL	53	10	2	0.029	0.18	0.077
2008	63 NL	51	6	6	0.034	0.17	0.12
2009	61 NL	51	6	4	0.032	0.16	0.11
2010	57 NL+32 BE	58	8	0	0.022	0.09	0.07
2011	52 NL+16 BE	53	4	1	0.021	0.12	0.06
2012	44 NL+13 BE	36	10	0	0.028	0.1	0.09

A MRL proposal based on monitoring data is usually calculated as the 95th percentile of a residue population; this approach means that the estimated maximum residue level encompasses at least 95 % of the residues (FAO, 2009).

In Figure 3-1 and Figure 3-2 the development of the residue situation is plotted which shows that overall the residue concentrations in pears are declining. Figure 3-2 demonstrates that 95th percentiles of targeted monitoring data are generally higher than those of the non-targeted monitoring data (Figure 3-1). Assuming an exponential degradation curve, the 95th percentile of the chlormequat residues in pears is expected to approach a level of 0.03 mg/kg in 2013/2014 considering the non-targeted monitoring results; based on the targeted monitoring data the predicted residue level for 2014 (95th percentile) is below 0.07 mg/kg, but it is noted that the results show a high degree of variations for both analysis (targeted and non-targeted samples). In particular, in 2012 the 95th percentiles in both scenarios were slightly higher than in 2011.

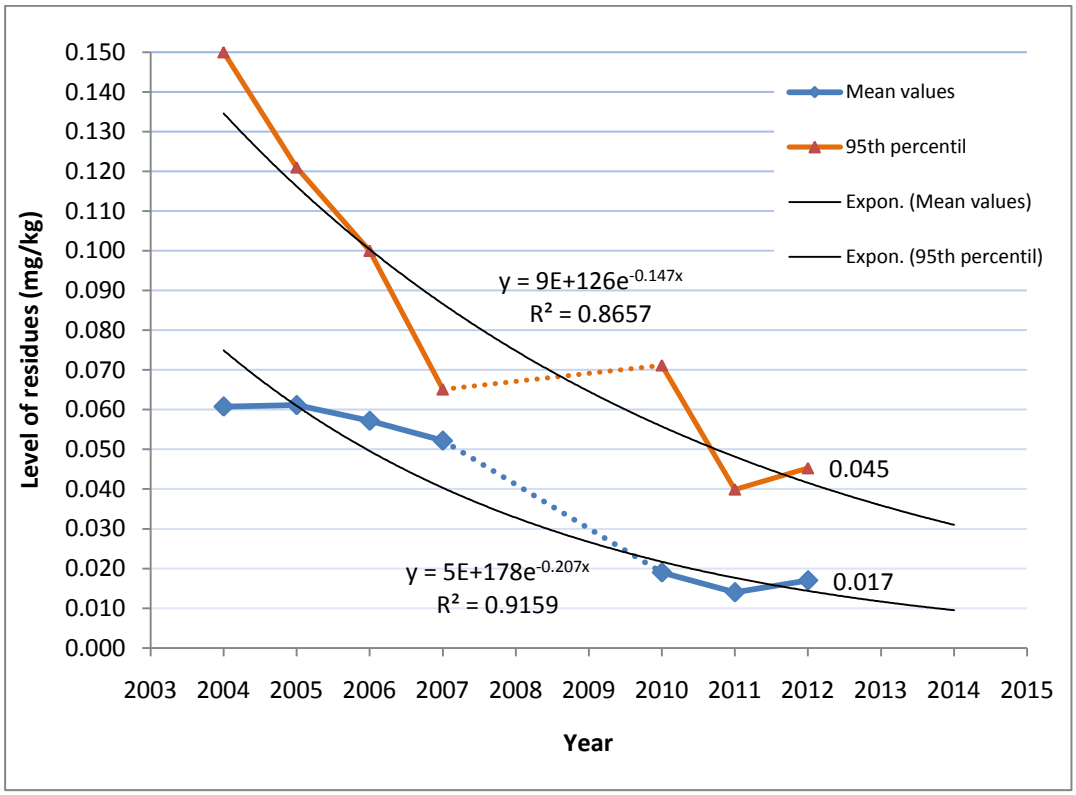


Figure 3-1: Decline of residues based on **non-targeted** monitoring data combined for Belgium and the Netherlands, including an exponential trend line for 95th percentiles and mean values.

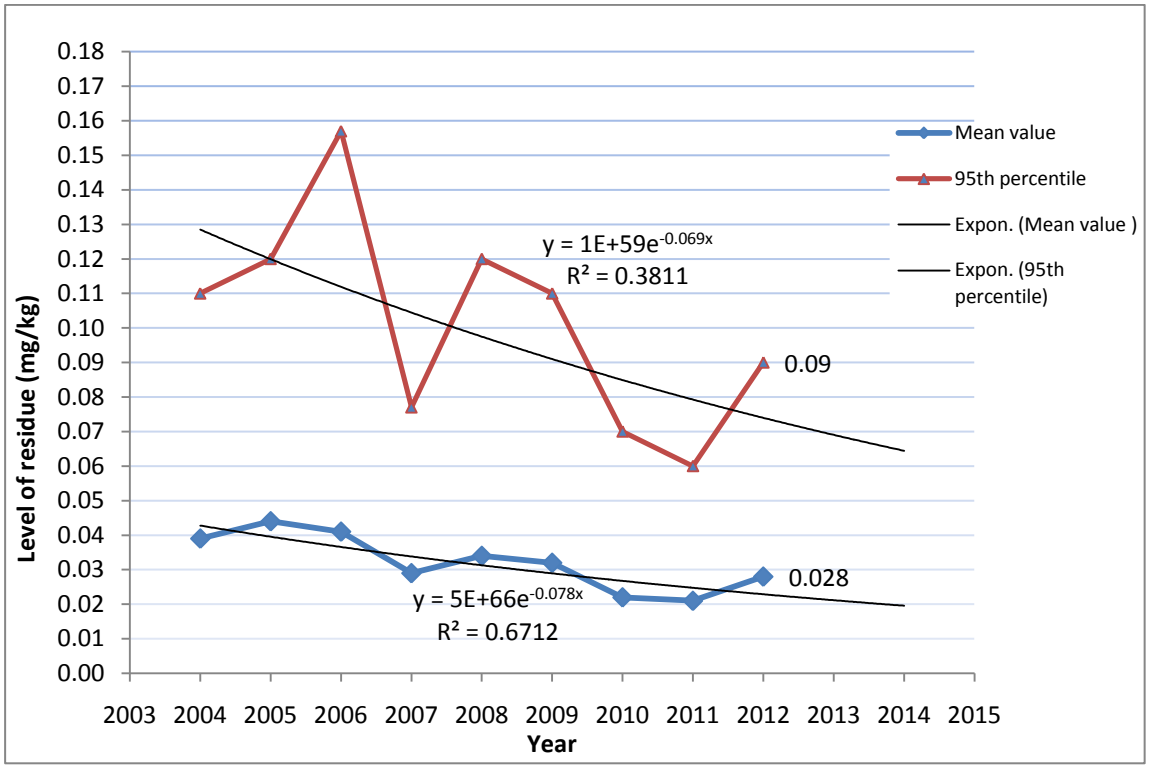


Figure 3-2: Decline of residues based **on targeted** monitoring data combined for Belgium and the Netherlands, including an exponential trend line for 95th percentiles and mean values.

The non-targeted monitoring data give an indication that for pears harvested in 2013 and onwards, the 95th percentile of residues will be below the LOQ of 0.05 mg/kg. Thus, based on a non-targeted monitoring data, the setting of temporary MRL for chlormequat in pears is no longer necessary. The targeted monitoring data, however, indicate that for the future, the 95th percentile of chlormequat residues in pears will be below the MRL of 0.1 mg/kg, but still above the LOQ of 0.05 mg/kg. In this case a risk management decision on the level of the temporary MRL and the period of its applicability has to be taken.

Cereals

The submitted residue trials on cereals were analysed for chlormequat chloride and residue data represent the residue definition derived by the peer review (*i.e.*, sum of chlormequat and its salts, expressed as chlormequat chloride). Since the existing MRLs are set for the enforcement residue definition chlormequat (cation), EFSA derived the risk assessment values and MRL proposals also for this residue definition, by applying the molecular weight conversion factor of 0.78.

b. Wheat

The applicant submitted six new residue trials on wheat grain as well as referred to four residue trials previously assessed in the framework of the peer review.

The residue trials provided in the DAR were all performed in Germany, the United Kingdom and northern France in 2003 and 2004. One trial from France (replicate trial) was disregarded because the control sample of grain contained substantial residues. The two trials from Germany were replicate trials and thus the average value was included in the residue data set; the third trial was performed with different application rates (0.7 kg a.s./ha and 1.5 kg a.s./ha) and only the results from the compliant trial were included in the residue data set.

Five of the new trials on wheat complied with the intended GAP and were performed in Germany and northern France in 2009. One trial from the UK was disregarded both by the EMS and EFSA due to a double application of chlormequat.

Finally, seven GAP compliant residue trials on wheat are available to support the intended NEU use. The submitted residue data indicate that a MRL of 2 mg/kg would be required for the residue definition proposed in the peer review (i.e., chlormequat chloride) and 1.5 mg/kg for the residue definition established in Regulation (EC) No 396/2005 (i.e., chlormequat (calculated as cation)). Since the existing MRL set for chlormequat (cation) is higher (2 mg/kg), no modification of the existing MRL is proposed for wheat grain in the framework of the current application. The residue data on wheat straw were also provided and indicate that, in case MRLs for feed are set in the future, a MRL of 50 mg/kg (for chlormequat chloride) or 40 mg/kg (for chlormequat (cation)) would be required for wheat straw.

c. Barley

The applicant submitted five new residue trials on barley grain as well as referred to three residue trials previously assessed in the framework of the peer review. The residue trials provided in the DAR were all performed with different application rates (0.7 kg a.s./ha and 1.5 kg a.s./ha) and only the results from compliant trials were included in the residue data set. Trials were performed in Germany, France and the United Kingdom in 2003. New residue trials were compliant with the GAP and were performed in France and Germany in 2009 and 2011.

A sufficient number of residue trials has been submitted to support the intended NEU use. The submitted residue data indicate that a MRL of 2 mg/kg would be required for the residue definition expressed as chlormequat chloride and 1.5 mg/kg for the residue definition chlormequat (calculated as cation). Since the existing EU MRL set for chlormequat (cation) is higher (2 mg/kg), no modification of the existing MRL is proposed for barley grain in the framework of the current application. The residue data on barley straw were also provided and indicate that, in case MRLs for feed are set in the future, a MRL of 50 mg/kg (for chlormequat chloride) or 40 mg/kg (for chlormequat (cation)) would be required to account for residues in barley straw.

d. Rye

In support of the intended use the applicant submitted in total nine GAP compliant residue trials on rye grain which have been performed in Germany and France in 2009 and 2010. Residue data are sufficient to derive a MRL of 4 mg/kg for the residue expressed as chlormequat chloride or 3 mg/kg for chlormequat (cation) to accommodate the NEU use of chlormequat on rye. The residue data submitted for rye straw indicate that, in case MRLs for feed are set in the future, a MRL of 15 mg/kg for chlormequat chloride or chlormequat (cation) would be required to account for residues in rye straw.

e. Oats

The applicant submitted in total eight GAP compliant residue trials on oat grain which have been performed in Germany and France in 2009 and 2010. In two residue trials the application of chlormequat was made at a later growth stage (BBCH 39[15]) than in the intended GAP (BBCH 37[16]); higher residues in grain and straw were observed in samples from these trials. The deviation, however, by two steps within a principal growth stage (stem elongation) is not considered a significant incompliance with the GAP and therefore these trials were included in the final residue data set. Residue data are sufficient to derive a MRL proposal of 15 mg/kg for chlormequat chloride or 9 mg/kg for chlormequat (cation) to accommodate the NEU use of chlormequat on oats. The residue data submitted for oat straw indicate that, in case MRLs for feed are set in the future, a MRL of 20 mg/kg

[15] BBCH 39: Flag leaf stage: flag leaf fully unrolled, ligule just visible.
[16] BBCH 37: Flag leaf just visible, still rolled.

(for chlormequat chloride) or 15 mg/kg (for chlormequat (cation)) would be required to account for residues in oat straw.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-4.

The storage stability of chlormequat chloride in primary crops was investigated in the DAR under Directive 91/414/EEC (United Kingdom, 2007; EFSA, 2008). Residues of chlormequat chloride were found to be stable at ≤ -18°C for up to 24 months in wheat grain and straw (EFSA, 2008). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (United Kingdom, 2013).

Table 3-4: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement	Risk assessment					
Enforcement residue definition: sum of chlormequat and its salts, expressed as chlormequat chloride *(the results in square brackets refer to the residue definition "Chlormequat" (calculated as cation)* **Risk assessment residue definition**: sum of chlormequat and its salts, expressed as chlormequat chloride *(the results in square brackets refer to the residue definition "Chlormequat" (calculated as cation)*									
Wheat grain	NEU	Outdoor	0.2; 0.3; 0.39; 0.47; 0.62; 0.78; 0.96 *[Chlormequat(cation): 0.16; 0.23; 0.31; 0.37; 0.48; 0.61; 0.75]*	0.2; 0.3; 0.39; 0.47; 0.62; 0.78; 0.96 *[Chlormequat(cation): 0.16; 0.23; 0.31; 0.37; 0.48; 0.61; 0.75]*	0.47 *[0.37]*	0.96 *[0.75]*	2 *[1.5]*[f]	1	R_{ber}= 1.56 R_{max}= 1.45 MRL_{OECD} = 1.62/2.0 Existing MRL for chlormequat is 2 mg/kg.
Barley grain	NEU	Outdoor	0.16; 0.22; 0.41; 0.47; 0.49; 0.64; 0.84; 0.99 *[Chlormequat (cation): 0.12; 0.17; 0.32; 0.37; 0.38; 0.50; 0.66; 0.77]*	0.16; 0.22; 0.41; 0.47; 0.49; 0.64; 0.84; 0.99 *[Chlormequat (cation): 0.12; 0.17; 0.32; 0.37; 0.38; 0.50; 0.66; 0.77]*	0.48 *[0.38]*	0.99 *[0.77]*	2 *[1.5]*[f]	1	R_{ber}=1.58 R_{max}=1.44 MRL_{OECD} = 1.67/2.0 Existing MRL for chlormequat is 2 mg/kg.
Rye grain	NEU	Outdoor	0.2; 0.32; 0.34; 0.38; 0.59; 0.67; 0.94; 1.0; 2.6 *[Chlormequat (cation): 0.16; 0.25; 0.27; 0.30; 0.46; 0.52; 0.73; 0.78; 2.03]*	0.2; 0.32; 0.34; 0.38; 0.59; 0.67; 0.94; 1.0; 2.6 *[Chlormequat (cation): 0.16; 0.25; 0.27; 0.30; 0.46; 0.52; 0.73; 0.78; 2.03]*	**0.59** ***[0.46]***	**2.6** ***[2.03]***	**4** ***[3.0]***[f]	**1**	R_{ber}=1.94 R_{max}=3.01 MRL_{OECD} = 3.73/4.0

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement	Risk assessment					
Enforcement residue definition: sum of chlormequat and its salts, expressed as chlormequat chloride *(the results in square brackets refer to the residue definition "Chlormequat" (calculated as cation)* **Risk assessment residue definition**: sum of chlormequat and its salts, expressed as chlormequat chloride *(the results in square brackets refer to the residue definition "Chlormequat" (calculated as cation)*									
Oat grain	NEU	Outdoor	2.3; 2.5; 2.6; 2.8; 3.4; 4.10; 4.3[g]; 7.4[g] *[Chlormequat (cation): 1.79; 1.95; 2.03; 2.18; 2.65; 3.20; 3.35; 5.77]*	2.3; 2.5; 2.6; 2.8; 3.4; 4.10; 4.3[g]; 7.4[g] *[Chlormequat (cation): 1.79; 1.95; 2.03; 2.18; 2.65; 3.20; 3.35; 5.77]*	**3.1** ***[2.42]***	**7.4** ***[5.77]***	**15** ***[9.0][f]***	**1**	R_{ber}=8.5 R_{max}=9.03 MRL_{OECD} = 11.03/15
Feed items									
Wheat straw	NEU	Outdoor	6.2; 8.1; 9.4; 13.39; 16.3; 24; 28.65 *[Chlormequat (cation): 4.84; 6.32; 7.33; 10.44; 12.71; 18.72; 22.35]*	6.2; 8.1; 9.4; 13.39; 16.3; 24; 28.65 *[Chlormequat (cation): 4.84; 6.32; 7.33; 10.44; 12.71; 18.72; 22.35]*	13.39 *[10.44]*	28.65 *[22.35]*	50 *[40][f]*	1	R_{ber}=48.0 R_{max}=43.9 MRL_{OECD} = 48.9
Barley straw	NEU	Outdoor	3.5; 4.1; 5.23; 6.7; 7.10; 7.27; 9.12; 34.0 *[Chlormequat (cation): 2.73; 3.2; 4.08; 5.23; 5.54; 5.67; 7.11; 26.52]*	3.5; 4.1; 5.23; 6.7; 7.10; 7.27; 9.12; 34.0 *[Chlormequat (cation): 2.73; 3.2; 4.08; 5.23; 5.54; 5.67; 7.11; 26.52]*	6.9 *[5.38]*	34 *[26.52]*	50 *[40][f]*	1	R_{ber}=17.3 R_{max}=41.6 MRL_{OECD} = 49.7

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement	Risk assessment					
Enforcement residue definition: sum of chlormequat and its salts, expressed as chlormequat chloride *(the results in square brackets refer to the residue definition "Chlormequat" (calculated as cation)* **Risk assessment residue definition**: sum of chlormequat and its salts, expressed as chlormequat chloride *(the results in square brackets refer to the residue definition "Chlormequat" (calculated as cation)*									
Rye straw	NEU	Outdoor	1.4; 1.4; 3.5; 4.3; 4.8; 5.2; 6.10; 7.1; 7.8 *[Chlormequat (cation): 1.09; 1.09; 2.73; 3.35; 3.74; 4.06; 4.76; 5.54; 6.08]*	1.4; 1.4; 3.5; 4.3; 4.8; 5.2; 6.10; 7.1; 7.8 *[Chlormequat (cation): 1.09; 1.09; 2.73; 3.35; 3.74; 4.06; 4.76; 5.54; 6.08*	4.8 *[3.74]*	7.8 *[6.08]*	15 *[15]*[f]	1	R_{ber}=13.2 R_{max}=11.5 MRL_{OECD} = 13.9
Oat straw	NEU	Outdoor	1.1; 2.5; 2.9; 4.1; 4.7; 6.0; 6.5[g]; 11.0[g] *[Chlormequat (cation): 0.86; 1.95; 2.26; 3.20; 3.67; 4.68; 5.07; 8.58]*	1.1; 2.5; 2.9; 4.1; 4.7; 6.0; 6.5[g]; 11.0[g] *[Chlormequat (cation): 0.86; 1.95; 2.26; 3.20; 3.67; 4.68; 5.07; 8.58]*	4.4 *[3.44]*	11 *[8.58]*	20 *[15]*[f]	1	R_{ber}=12.8 R_{max}=14.6 MRL_{OECD} = 17.12

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
(f): Residue expressed as chlormequat, by applying the molecular weight conversion factor of 0.78 to residue trials data.
(g): Last application of the active substance at the BBCH 39 (instead of BBCH 37).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of chlormequat chloride was investigated in the framework of the peer review in studies simulating beer brewing (100°C at pH 4 for 120 minutes) and bread making (100°C at pH 5 for 40 minutes) (United Kingdom, 2007). Under both conditions a decline (*ca.* 9-14 % AR) in the total amounts of chlormequat chloride and a formation of four minor degradation products was observed. All degradation products were individually below 5 % of the applied radioactivity and a further characterisation was not undertaken. EFSA concludes that for the processing conditions relevant for cereals, chlormequat will be the main residue of concern in processed commodities and therefore the same residue definition as in raw commodity is applicable. In order to derive a general residue definition for processed commodities, additional studies investigating the nature of chlormequat under sterilisation and pasteurization conditions would be required.

No new studies to assess the magnitude of chlormequat chloride residues during the processing of cereals or pears have been submitted. Several processing studies with wheat, barley and oats have been assessed in the framework of the peer review and the following processing factors (see Table 3-5) for wheat bran, flour, bread, pot barley, malt, beer and oat flakes were derived (EFSA, 2008):

Table 3-5: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: sum of chlormequat and its salts, expressed as chlormequat chloride (proposed in the peer review, EFSA, 2008)				
Wheat, bran	4	3.1	-	EFSA, 2008.
Wheat, flour (type 550)	4	0.3	-	
Wheat, wholemeal flour	4	1.0	-	
Wheat, wholegrain bread	4	0.5	-	
Barley, pot barley	4	0.9	-	
Barley, malt	4	0.9	-	
Barley, beer	4	0.2	-	
Oats, flakes	4	0.9	-	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Cereals are grown in rotation with other plants and therefore the possible occurrence of chlormequat residues in succeeding crops resulting from the use on primary crops has to be investigated. According to the laboratory soil degradation studies assessed in the framework of the peer review, the DT_{90} value for the degradation of chlormequat in the soil exceeds the trigger value of 100 days. No other relevant soil metabolites were identified. According to the EC guidelines (EC, 1997c), further studies investigating the nature and magnitude of the compound uptake in rotational crops are required.

3.1.2.2. Nature of residues

The metabolism of ^{14}C-chlormequat chloride in rotational crops was investigated in two studies submitted for the peer review (United Kingdom, 2007; 2008). The overview of the study designs is presented in the table below.

Table 3-6: Overview of the available confined rotational crop studies

Crop group	Crop sown	Application details			
		Method	Rate (kg a.s./ha)	Sowing intervals	Harvest time
Chlormequat chloride					
Leafy vegetable	Lettuce	Soil	2.0	a) 30 DAT; b) 120 and 365 DAT (after harvest of first rotation lettuce)	a) maturity; b) immature and mature
		Soil	1.51	30 DAT	Immature and mature
Root and tuber vegetables	Radish	Soil	2.0	30 DAT; b) 120 and 365 DAT (after harvest of first rotation radish)	a) maturity; b) immature and mature
	Carrots	Soil	1.51	30 DAT	Immature and mature
Cereals	Spring wheat	Soil	2.0	30 DAT; b) 120 and 365 DAT (after harvest of first rotation wheat)	a) and b) immature and mature (forage) and mature grain, straw, chaff
		Soil	1.51	30 DAT	Immature and mature
Pulses and oilseeds	Green beans	Soil	1.51	30 DAT	Immature and mature

In the first rotational crop study, the soil was treated with chlormequat chloride at an application rate of 2 kg a.s./ha and rotational crops were planted 30, 120 and 365 days of aging. The TRR was relatively low in lettuce and radish for all three plant-back intervals (max. 0.021 mg eq./kg, 0.046 mg eq./kg and 0.037 mg eq./kg in lettuce, radish leaves and radish roots, respectively). Considerable concentrations of radioactive residues were found in wheat (max. 0.153 mg eq./kg, 0.336 mg eq./kg, 0.229 mg eq./kg and 0.197 mg eq./kg in forage, straw, chaff and grain respectively). Besides chlormequat, further polar compounds were found but could not be identified (EFSA, 2008).

In the second rotational crop study, soil was treated with chlormequat chloride at a rate equivalent to 1.5 kg a.s./ha. After ageing of the soil for 30 days rotational crops were planted. Low concentrations of TRR were found in beans, carrot and lettuce (max. 0.01 mg eq./kg in crop parts for human consumption; 0.052 mg eq./kg, 0.041 mg eq./kg and 0.066 mg eq./kg were found in wheat grain, forage and straw, respectively) (EFSA, 2008).

Although the peer review noted poor identification of metabolites in lettuce, radish and wheat in the first study, it is assumed that the metabolic pattern in the rotational crops would be similar to the metabolic pattern depicted in the primary crop (wheat metabolism study) with a considerable amount of radioactivity incorporated into the matrix (EFSA, 2008). The peer review asked the applicant to provide a clarification for the considerably lower residues in the second study compared to the first study. In the framework of the current application, the applicant explained these differences by higher application rates in the first study and by different ways of preparing soil to simulate ploughing in the second study (United Kingdom, 2013).

Both studies indicated that the total residues recovered in wheat were significant. Thus, the peer review concluded that residues of chlormequat may be of concern when cereals are planted as rotational crops on the fields previously treated with chlormequat; residues in rotated cereals, however, should not be higher than in cereals directly treated with chlormequat chloride according to the notified GAP (EFSA, 2008). The intended uses on cereals assessed in the framework of the current application are identical to the GAPs submitted for the peer review and therefore the same conclusions are applicable. In order to avoid residues of chlormequat in cereals when planted as rotational crops, the Member States, when granting authorisations of chlormequat shall apply the necessary risk mitigation measures.

3.1.2.3. Magnitude of residues

No rotational crop field studies have been submitted for the peer review or under the current application. For the magnitude of residues in rotational crops see section above.

3.2. Nature and magnitude of residues in livestock

Since cereals and their by-products can be fed to livestock, the nature of chlormequat in livestock and a possible carry-over of residues into food commodities of animal origin has to be assessed.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations (FAO, 2009) considering the livestock intake from cereals and from all other feed products for which the existing EU MRL according to the Regulation (EC) No 396/2005 is set above the LOQ (linseed and rape seed).

To conduct these calculations, EFSA used the risk assessment values as derived for cereals from the residue trials submitted under the current application (Table 3-4). In order to account for the concentration of residues in wheat bran and rye bran, a processing factor of 3.1, as derived in the framework of the peer review for wheat bran (Table 3-5) was applied. For rape seed and linseed the risk assessment values were as reported by France in the framework of the setting of temporary MRLs (France, 2007). Processing factor of 1.13 as derived by the JMPR was applied to express residues in oilseed meal (FAO, 1994).

The input values for the dietary burden calculation are summarised in Table 3-7.

Table 3-7: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Risk assessment residue definition: sum of chlormequat and its salts, expressed as chlormequat chloride				
Wheat grain	0.47	Median residue (Table 3-4)	0.47	Median residue (Table 3-4)
Barley grain	0.48	Median residue (Table 3-4)	0.48	Median residue (Table 3-4)
Rye grain	0.59	Median residue (Table 3-4)	0.59	Median residue (Table 3-4)
Oat grain	3.1	Median residue (Table 3-4)	3.1	Median residue (Table 3-4)
Wheat straw	13.39	Median residue (Table 3-4)	28.65	Highest residue (Table 3-4)
Barley straw	6.9	Median residue (Table 3-4)	34	Highest residue (Table 3-4)

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Rye straw	4.8	Median residue (Table 3-4)	7.8	Highest residue (Table 3-4)
Oats straw	4.4	Median residue (Table 3-4)	11	Highest residue (Table 3-4)
Wheat bran	1.46	Median residue (grain) (Table 3-4) * PF (3.1) (Table 3-5)	1.46	Median residue (grain) (Table 3-4) * PF (3.1) (Table 3-5)
Rye bran	1.83	Median residue (grain) (Table 3-4) * PF (3.1) (Table 3-5)	1.83	Median residue (grain) (Table 3-4) * PF (3.1) (Table 3-5)
Rape seed[b] meal	2.9[a]	Median residue (2.25) (France, 2007) * PF (1.13) (FAO, 1994)	2.9[a]	Median residue (2.25) (France, 2007) * PF (1.13) (FAO, 1994)
Linseed[b] meal	2.9[a]	Median residue (2.25) (France, 2007) * PF (1.13) (FAO, 1994)	2.9[a]	Median residue (2.25) (France, 2007) * PF (1.13) (FAO, 1994)

(a): Residues expressed as chlormequat chloride (FAO, 1994).
(b): According to Commission Directive 2010/2/EU, chlormequat cannot be authorized on oilseed in Europe.

The results of the dietary burden calculation are summarised in the following table.

Table 3-8: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw per day)	**Median dietary burden** (mg/kg bw per day)	**Highest contributing commodity**[(a)]	**Max dietary burden** (mg/kg DM)	**Trigger exceeded** (Y/N)
Risk assessment residue definition: sum of chlormequat and its salts, expressed as chlormequat chloride					
Dairy ruminants	0.377	0.202	Barley straw	10.4	Y
Meat ruminants	0.924	0.411	Barley straw	21.5	Y
Poultry	0.181	0.181	Oat grain	2.9	Y
Pigs	0.142	0.142	Oat grain	3.6	Y

The calculated dietary burden indicates that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all livestock species and is mainly driven by the uses on barley and oats. Thus, the potential carry-over of chlormequat residues into food of animal origin has to be further assessed.

3.2.2. Nature of residues

The metabolism of ^{14}C-chlormequat chloride in livestock (goats and hens) was assessed in the DAR prepared under Directive 91/414/EEC (United Kingdom, 2007) and in the conclusions of the peer review (EFSA, 2008).

In lactating goats dosed at 62.5 mg of chlormequat (28.9 mg/kg diet as received) for 7 consecutive days, the majority of the applied radioactivity was found in excreta (49 % in urine, 30 % in faeces and 0.6 % in milk). Tissues accounted only for 0.13 % of the applied dose (0.36 mg eq./kg TRR in liver, 1.45 mg eq./kg TRR in kidney, 0.23 mg eq./kg TRR in muscle and 0.030 mg eq./kg TRR in fat). Organic extraction recovered 67 % of TRR in fat and 77-92 % of TRR in other tissues, but only 17-20 % of TRR in milk. Chlormequat accounted for 42 %, 83 %, 76 % and 4 % of TRR in the organic

extracts of liver, kidney, muscle and milk respectively. No further metabolites were identified (EFSA, 2008).
For laying hens dosed at 3.0 mg chlormequat for 14 consecutive days the majority of the radioactivity was recovered in excreta (92.6 %). Egg white and egg yolk contained 0.05 % and 0.34 % of the administered radioactivity, tissues only approximately 0.04 %. In kidney, liver, muscle and abdominal fat TRR of 0.35 mg eq./kg, 0.36 mg eq./kg kg, 0.12 mg eq./kg and 0.06 mg eq./kg were found. Organic extraction recovered 65 % of TRR in liver and kidney, 75 % in muscle and 62-69 % in egg yolk, but only 6 % in egg white and 15 % in fat. Only in one of the egg yolk samples a substantial amount of the radioactive residues (0.21 mg eq./kg, 21.6 %) remained unextracted. Chlormequat was the only identified component of the residue. It was present at levels of 6.5 % TRR (0.023 mg/kg) in kidney, 1.8 % (0.007 mg/kg) TRR in liver and 48 % TRR (0.47 mg/kg) in one egg yolk sample.

After oral administration of chlormequat chloride to goats or hens, residues are rapidly excreted. Only small amounts of residues are transferred to tissues, milk or eggs (EFSA, 2008). The peer review concluded that, generally, the metabolism in ruminants and non-ruminants proceeds in a similar pathway. The residue definition for the risk assessment and enforcement in livestock was set as the "sum of chlormequat and its salts, expressed as chlormequat chloride" (EFSA, 2008). The metabolism studies also confirmed that chlormequat residues are not fat-soluble.

3.2.3. Magnitude of residues

Livestock feeding studies were carried out with chlormequat chloride on dairy cows (dose levels of 12, 36 and 120 mg/kg feed, corresponding to 0.38, 1.09, 3.75 mg/kg bw per day for 28 consecutive days) and laying hens (dose levels of 6, 18 and 60 mg/kg feed, corresponding to 0.38, 1.14 and 3.8 mg/kg bw for 28 days) and were assessed in the DAR (United Kingdom, 2007) and in the conclusion of the peer review (EFSA, 2008).

The storage stability of chlormequat chloride residues in animal matrices (milk, meat and eggs) has been investigated in the framework of the peer review and results indicated that chlormequat residues are stable for 12 months in deep frozen matrices (EFSA, 2008).

The median and highest calculated livestock dietary burdens (Table 3-8) and the mean and maximum residue values in animal matrices from the livestock feeding studies were used according to the FAO recommendations to derive MRL proposals and risk assessment values for animal commodities (FAO, 2009). It is noted that results of the dietary burden calculation as well as of the livestock feeding studies are expressed as chlormequat chloride, according to the residue definition derived by the peer review. In order to derive residue values expressed as chlormequat (cation) according to Regulation (EC) No 396/2005, a molecular weight conversion factor of 0.78 was applied. Thus, EFSA derived two MRL proposals – one for chlormequat chloride and one for chlormequat (cation). The overview of the feeding study results, the derived risk assessment values and the MRL proposals are summarised in Table 3-9.

The results of the feeding studies indicate that at the calculated livestock dietary burdens the existing MRLs for chlormequat (cation) have to be raised only for ruminant muscle (to 0.08 mg/kg), liver (to 0.12 mg/kg), kidney (to 0.4 mg/kg), for swine kidney (to 0.12 mg/kg) and milk (to 0.06 mg/kg).

Since the review of the existing MRLs for chlormequat according to Article 12 of Regulation (EC) No 396/2005 has not been finalized yet, the calculated MRL proposals for commodities of animal origin have to be considered as provisional.

Table 3-9: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study				Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	
	Median (mg/kg bw per day)	Max. (mg/kg bw per day)	Dose Level (mg/kg bw per day)	No.	Enforcement and risk assessment residue definition (sum of chlormequat and its salts, expressed as chlormequat chloride)				Sum of chlormequat and its salts, expressed as chlormequat chloride (EFSA, 2008)	Chlormequat (calculated as cation) (Reg. (EC) No 396/2005)
					Mean (mg/kg)	Max. (mg/kg)				
Ruminant muscle	0.411	0.924	0.38	3	<0.05	<0.05	**0.05** (meat: 0.05)	**0.096** (meat: 0.09)	**0.1**	**0.08**
			1.09	3	<0.05	0.11				
			3.75	5	<0.05	0.07				
Ruminant fat	0.411	0.924	0.38	3	<0.05	0.05	**0.05**	**0.05**	**0.05**	<0.05
			1.09	3	<0.05	0.05				
			3.75	5	0.08	0.1				
Ruminant liver	0.411	0.924	0.38	3	0.08	0.10	**0.09**	**0.13**	**0.15**	**0.12**
			1.09	3	0.09	0.09				
			3.75	5	0.38	0.5				
Ruminant kidney	0.411	0.924	0.38	3	0.16	0.30	**0.17**	**0.42**	**0.5**	**0.4**
			1.09	3	0.40	0.46				
			3.75	5	0.76	1.06				
Pig muscle	0.142	0.142	0.38	4	<0.05	<0.05	<0.05 (meat: 0.05)	<0.05 (meat: 0.05)	<0.05	<0.05
			1.09	4	<0.05	0.11				
			3.75	12	<0.05	0.07				

Commodity	Dietary burden		Results of the livestock feeding study				Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	
	Median (mg/kg bw per day)	Max. (mg/kg bw per day)	Dose Level (mg/kg bw per day)	No.	Enforcement and risk assessment residue definition (sum of chlormequat and its salts, expressed as chlormequat chloride)				Sum of chlormequat and its salts, expressed as chlormequat chloride (EFSA, 2008)	Chlormequat (calculated as cation) (Reg. (EC) No 396/2005)
					Mean (mg/kg)	Max. (mg/kg)				
Pig fat	0.142	0.142	0.38	4	<0.05	0.05	<0.05	<0.05	<0.05	<0.05
			1.09	4	<0.05	0.05				
			3.75	12	0.08	0.1				
Pig liver	0.142	0.142	0.38	4	0.08	0.10	<0.05	<0.05	<0.05	<0.05
			1.09	4	0.09	0.09				
			3.75	12	0.38	0.5				
Pig kidney	0.142	0.142	0.38	4	0.16	0.30	**0.06**	**0.11**	**0.15**	**0.12**
			1.09	4	0.40	0.46				
			3.75	12	0.76	1.06				
Poultry muscle	0.181	0.181	0.38[a]	4	<0.05	<0.05	<0.05 (meat: 0.05	<0.05 (meat: 0.05)	<0.05	<0.05
			1.14[a]	4	<0.05	<0.05				
			3.8[a]	12	<0.05	<0.05				
Poultry fat	0.181	0.181	0.38[a]	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
			1.14[a]	4	<0.05	<0.05				
			3.8[a]	12	<0.05	<0.05				
Poultry liver	0.181	0.181	0.38[a]	4	0.05	0.05	<0.05	<0.05	<0.05	<0.05
			1.14[a]	4	0.07	0.07				

Commodity	Dietary burden		Results of the livestock feeding study				Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	
	Median (mg/kg bw per day)	Max. (mg/kg bw per day)	Dose Level (mg/kg bw per day)	No.	Enforcement and risk assessment residue definition (sum of chlormequat and its salts, expressed as chlormequat chloride)				Sum of chlormequat and its salts, expressed as chlormequat chloride (EFSA, 2008)	Chlormequat (calculated as cation) (Reg. (EC) No 396/2005)
					Mean (mg/kg)	Max. (mg/kg)				
			3.8[a]	12	0.09	0.18				
Milk	0.202	0.377	0.38	3	0.05	0.08	**0.03**	**0.066**	**0.07**	**0.06**
			1.09	3	0.19	0.26				
			3.75	5	0.22	0.65				
Eggs	0.181	0.181	0.38[a]	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
			1.14[a]	4	<0.05	0.1				
			3.8[a]	12	0.07	0.11				

(a): Based on 1.9 kg hen consuming 0.12 kg feed DM per day (EC, 1996).
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[17] (EFSA, 2007).

As the existing EU MRLs are set for the residue definition "chlormequat" (cation), the exposure assessment was performed for this residue definition and, when values were available for chlormequat chloride, those were expressed as chlormequat, by applying the molecular weight conversion factor of 0.78. For the calculation of chronic exposure, EFSA used the median residue values for wheat, rye, barley and oat grain as derived from the residue trials submitted in the framework of the current application (Table 3-4). For pears the mean residue as derived from the non-targeted monitoring data of 2012 (Table 3-2) was used as an input value. For commodities of animal origin the risk assessment values as derived in the framework of the current application (Table 3-9) were used as input values. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration, assuming the consumption of a large portion of the food items as reported in the national food surveys; for cereals the short-term exposure is calculated on the basis of the median residue concentration observed in supervised residue trials, for pears the MRL was used as input value while for food of animal origin the highest expected residue level was used, except for milk. Since milk is usually bulked before reaching the consumer, the median residue level is according to the international methodology to be used for short-term exposure calculations. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation for pears (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Chlormequat (cation)				
Pear	0.017	Mean residue (Table 3-2)	0.1	MRL
Rye grain	0.46	Median residue (Table 3-4)	0.46	Median residue (Table 3-4)
Oats grain	2.42	Median residue (Table 3-4)	2.42	Median residue (Table 3-4)
Wheat grain	0.37	Median residue (Table 3-4)	0.37	Median residue (Table 3-4)

[17] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley grain	0.38	Median residue (Table 3-4)	0.38	Median residue (Table 3-4)
Ruminant meat	0.04	Median residue (meat) (Table 3-9)* CF (0.78)	0.07	Highest residue (meat) (Table 3-9)*CF (0.78)
Ruminant fat	0.04	Median residue (Table 3-9)* CF (0.78)	0.04	Highest residue (Table 3-9)*CF (0.78)
Ruminant liver	0.07	Median residue (Table 3-9)* CF (0.78)	0.10	Highest residue (Table 3-9)*CF (0.78)
Ruminant kidney	0.13	Median residue (Table 3-9)* CF (0.78)	0.33	Highest residue (Table 3-9)*CF (0.78)
Swine kidney	0.05	Median residue (Table 3-9)* CF (0.78)	0.09	Highest residue (Table 3-9)*CF (0.78)
Swine meat, fat, liver	0.04	Median residue (Table 3-9)* CF (0.78)	0.04	Highest residue (Table 3-9)*CF (0.78)
Poultry meat, fat, liver	0.04	Median residue (Table 3-9)* CF (0.78)	0.04	Highest residue (Table 3-9)*CF (0.78)
Milk	0.02	Median residue (Table 3-9)* CF (0.78)	0.02	Median residue (Table 3-9)* CF (0.78)
Eggs	0.04	Median residue (Table 3-9)* CF (0.78)	0.04	Highest residue (Table 3-9)*CF (0.78)
Other commodities of plant and animal origin	MRL	See Appendix C	Acute risk assessment was undertaken only with regard to the crops under consideration.	

The estimated exposure was then compared with the toxicological reference values derived for chlormequat (calculated as cation) (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 27 % of the ADI (WHO Cluster diet E). The individual contribution of residues in the crops under consideration to the total consumer exposure (in percentage of the ADI) accounted for 10 % for wheat (WHO Cluster diet B), 6 % for rye and 3 % for oat (DK child diet), 1.5 % for barley (IE adult diet) and 0.04 % for pears (DK child diet). The contribution of chlormequat residues in milk accounted for 3 % of the ADI and was individually below 0.2 % of the ADI other animal commodities under consideration.

No acute consumer risk was identified in relation to the MRL proposal for pears and for the intended use on rye and oat grain and resulting residues in commodities of animal origin. The calculated maximum exposure in percentage of the ARfD was 14 % for oats, 13 % for pears, 8 % for wheat, and below 5 % other commodities under consideration.

EFSA concludes that the temporary MRL for pears and the new intended use of chlormequat on rye and oat grain and the resulting residues in animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of chlormequat was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.04 mg/kg bw per day and an ARfD of 0.09 mg/kg bw for chlormequat chloride.

The metabolism of chlormequat chloride in primary crops was investigated in cereals only, for which the peer review concluded to establish the residue definition for enforcement and risk assessment as the "sum of chlormequat and its salts, expressed as chlormequat chloride". No metabolism studies are available for chlormequat in fruits. Considering that the existing temporary MRL in pears is set for chlormequat, it is proposed to define the relevant residue in pears as chlormequat under the current MRL application. For the intended uses on cereals EFSA concludes that the metabolism of chlormequat is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable. The enforcement residue definition according to Regulation (EC) No 396/2005 is set as chlormequat (cation).

The EMS NL submitted targeted (1998-2012) and non-targeted (2010-2012) monitoring data from the Netherlands and Belgium on residue levels of chlormequat (cation) in pears. The non-targeted monitoring data give an indication that for pears harvested in 2013 and onwards, the 95th percentile of residues will be below the LOQ of 0.05 mg/kg. Thus, based on a non-targeted monitoring data, the setting of temporary MRL for chlormequat in pears is no longer necessary. The targeted monitoring data (2004-2012), however, indicate that for the future years, the 95th percentile of chlormequat residues in pears will be below the MRL of 0.1 mg/kg, but still above the LOQ of 0.05 mg/kg.

The submitted supervised residue field trials on cereals indicate that in order to accommodate the intended NEU use, a higher MRL of 4 mg/kg in rye grain and 15 mg/kg in oats grain would be required for chlormequat chloride corresponding to 3 mg/kg and 9 mg/kg, respectively, for chlormequat (cation). Adequate analytical enforcement methods are available to control chlormequat residues in the crops under consideration.

The effect of processing on the nature of chlormequat chloride was investigated in studies simulating beer brewing and bread making and under these conditions no degradation of chlormequat was observed. EFSA concludes that in processed cereals chlormequat will be the main residue of concern. In order to derive a general residue definition for processed commodities, additional studies investigating the nature of chlormequat under sterilisation and pasteurization conditions would be required. New studies to assess the magnitude of chlormequat residues during the processing of the crops under consideration have not been submitted in the framework of the current application. Such studies with cereals have been assessed in the framework of the peer review.

The occurrence of chlormequat chloride in rotational crops was investigated under the peer review, which concluded that residues of chlormequat may be of concern when cereals are planted as rotational crops but noted that residues in rotated cereals should not be higher than in cereals directly treated with chlormequat chloride according to the notified uses. Thus, in order to avoid residues of chlormequat in cereals when planted as rotational crops, the Member States, when granting authorisations of chlormequat shall apply the necessary risk mitigation measures.

Cereals and their by products can be fed to livestock and therefore the potential carry-over of chlormequat residues into food of animal origin was assessed. The calculated livestock dietary burdens exceed the trigger value of 0.1 mg/kg (dry matter) for all relevant livestock species and are driven by uses on barley and oats. The peer review concluded that, generally, the metabolism in ruminants and non-ruminants proceeds in a similar pathway and that the residue definition for the risk assessment and enforcement in livestock is set as the "sum of chlormequat and its salts, expressed as chlormequat chloride". The livestock feeding studies were used to estimate the carry-over of chlormequat chloride

residues into food of animal origin at the calculated dietary burdens. The results of the feeding studies indicate that at the calculated livestock dietary burdens the existing MRLs for chlormequat (cation) have to be raised for ruminant meat, liver and kidney, swine kidney and milk. An adequate analytical enforcement method is available to control chlormequat residues in food of animal origin.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The existing MRLs are set for chlormequat (cation) and therefore the risk assessment values which were available for chlormequat chloride were expressed as chlormequat (cation), by applying the molecular weight conversion factor. For the calculation of chronic exposure, EFSA used the median residue values for cereals as derived from the submitted residue trials. For pears the mean value derived from non-targeted monitoring data of 2012 was used as an input value. For commodities of animal origin the risk assessment values were used as input values. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for chlormequat.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 27 % of the ADI (WHO Cluster diet E). The individual contribution of residues in the crops under consideration to the total consumer exposure (in percentage of the ADI) accounted for 10 % for wheat (WHO Cluster diet B), 6 % for rye and 3 % for oat (DK child diet), 1.5 % for barley (IE adult diet) and 0.04 % for pears (DK child diet). The contribution of chlormequat residues in milk accounted for 3 % of the ADI and was individually below 0.2 % of the ADI other animal commodities under consideration.

No acute consumer risk was identified in relation to the MRL proposal for pears and for the intended use on rye and oat grain and resulting residues in commodities of animal origin. The calculated maximum exposure in percentage of the ARfD was 14 % for oats, 13 % for pears, 8 % for wheat, and below 5 % other commodities under consideration.

EFSA concludes that the temporary MRL for pears and the intended use of chlormequat on rye and oats and the subsequent residues in animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Chlormequat[b]				
0130020	Pears	0.1 (until 31 July 2014)	0.1	The submitted residue data indicate that in general the residues in pears produced in the Netherlands and Belgium are declining. In 2013 and onwards 95 % of the samples of pears produced in the Netherlands and Belgium in areas where chlormequat was used in pear orchards in the past (before 2003) will contain residues at or below the level of 0.1 mg/kg. Risk managers to decide if and for how long the current temporary MRL should be maintained. The corresponding MRL proposal for chlormequat chloride is

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Chlormequat[b]				
				0.15 mg/kg.
0500010	Barley	2	No change	The submitted residue data indicate that a lower MRL of 1.5 mg/kg for chlormequat would be sufficient. The lowering, however, is not proposed since more critical uses of chlormequat on cereals might exist, requiring the existing MRL. The corresponding MRL proposal for chlormequat chloride is 2 mg/kg.
0500050	Oats	5	9	The MRL proposals are sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 15 mg/kg in oats and 4 mg/kg in rye.
0500070	Rye	2	3	
0500090	Wheat	2	No change	The submitted residue data indicate that a lower MRL of 1.5 mg/kg would be sufficient. The lowering, however, is not proposed since more critical uses of chlormequat on cereals might exist, requiring the existing MRL. The corresponding MRL proposal for chlormequat chloride is 2 mg/kg.
1011040	Swine kidney	0.05*	0.12	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.15 mg/kg.
1012010 1013010 1014010 1015010 1017010	Ruminant muscle	0.05*	0.08	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.1 mg/kg.
1012020 1013020 1014020 1015020 1017020	Ruminant fat	0.05*	No change	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.05 mg/kg.
1012030 1013030 1014030 1015030 1017030	Ruminant liver	0.1*	0.12	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.15 mg/kg.
1012040 1013040 1014040 1015040 1017040	Ruminant kidney	0.2*	0.4	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.5 mg/kg.
2030000	Milk	0.05*	0.06	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. The corresponding MRL proposal for chlormequat chloride is 0.07 mg/kg.

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): Residue calculated as cation.
(*): Indicates that the MRL is set at the limit of analytical quantification.

REFERENCES

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.

EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.

EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance chlormequat. EFSA Scientific Report 2008r 179, 1-77 pp.

EFSA (European Food Safety Authority), 2009. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for chlormequat in pears. EFSA Scientific Report 2009r 232, 1-34 pp.

FAO (Food and Agriculture Organisation of the United Nations), 1994. Chlormequat In: Pesticide residues in food—1994. Evaluations. Part I. Residues. 1-69 pp.

FAO (Food and Agriculture Organisation of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 1-271 pp.

FAO (Food and Agriculture Organisation of the United Nations), 2010. Pesticide residues in food 2010. Report of the Joint FAO/WHO Meeting on Pesticide residues. FAO Plant Production and Protection Paper 200, p.13.

France, 2007. MRL proposal-chlormequat on rape seed only- request change to EC provisional MRL on behalf of France. MRL evaluation filenote. December 2007, 13 pp.

Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.

The Netherlands, 2013. Evaluation report on the extend of the temporary MRLs for chlormequat (chloride) in pears prepared by the evaluating Member State Netherlands under Article 8 of Regulation (EC) No 396/2005, May 2013, 26 pp.

The United Kingdom, 2007. Draft assessment report on the active substance chlormequat prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, April 2007.

The United Kingdom, 2008. Addendum to the draft assessment report on the active substance chlormequat prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, April 2008.

The United Kingdom, 2013. Evaluation report on the review of the existing MRLs for chlormequat prepared by the evaluating Member State united Kingdom under Article 8 of Regulation (EC) No 396/2005, 4 June 2013, 68 pp.

APPENDICES

Appendix A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Wheat, barley, rye, triticale, oats	UK	F	Plant growth regulator	SL	750 g a.s./L	spray	BBCH 37 (stem elongation)	1	-	0.375-1.5	100-400	1.5	-	

Remarks:
(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMO)

Chlormequat			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,031**	ARfD (mg/kg bw):	**0,07**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
4	27
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
27	WHO cluster diet E	13	Rape seed	5	Wheat	3	Cultivated fungi	3
22	IE adult	8	Cultivated fungi	3	Linseed	3	Wheat	5
21	DK child	7	Wheat	7	Rye	3	Oats	3
20	NL child	6	Wheat	4	Cultivated fungi	2	Milk and cream,	9
18	WHO Cluster diet B	10	Wheat	1	Cultivated fungi	1	Olives for oil production	5
18	WHO Cluster diet F	7	Rape seed	4	Wheat	1	Oats	3
18	DE child	5	Wheat	3	Cultivated fungi	2	Apples	7
14	UK Toddler	5	Wheat	4	Sugar beet (root)	2	Cultivated fungi	7
13	WHO cluster diet D	8	Wheat	1	Potatoes	1	Rye	3
13	WHO regional European diet	4	Wheat	3	Rape seed	2	Cultivated fungi	3
12	UK Infant	3	Wheat	2	Milk and cream,	2	Oats	7
11	IT kids/toddler	8	Wheat	1	Cultivated fungi	0	Other cereal	2
11	ES child	5	Wheat	1	Milk and cream,	1	Milk and milk products: Cattle	4
10	FR toddler	3	Wheat	3	Milk and cream,	1	Potatoes	6
9	UK vegetarian	4	Cultivated fungi	2	Wheat	1	Sugar beet (root)	2
9	NL general	3	Cultivated fungi	2	Wheat	0	Barley	3
8	SE general population 90th percentile	4	Wheat	1	Milk and cream,	1	Milk and cream,	4
8	ES adult	3	Wheat	2	Cultivated fungi	1	Barley	2
8	PT General population	5	Wheat	1	Potatoes	0	Wine grapes	2
8	IT adult	5	Wheat	2	Cultivated fungi	0	Tomatoes	1
7	DK adult	2	Wheat	1	Cultivated fungi	1	Rye	2
7	FR infant	2	Milk and cream,	2	Milk and cream,	1	Wheat	6
7	FR all population	4	Wheat	1	Wine grapes	0	Rape seed	2
6	UK Adult	2	Wheat	2	Cultivated fungi	1	Sugar beet (root)	2
6	LT adult	2	Rye	1	Wheat	1	Oats	2
6	PL general population	4	Cultivated fungi	1	Potatoes	0	Apples	2
4	FI adult	1	Wheat	1	Rye	1	Oats	1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Chlormequat is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
14	Oats	2,42 / -	14	Oats	2,42 / -
13	Pears	0,1 / -	9	Pears	0,1 / -
8	Wheat	0,37 / -	8	Wheat	0,37 / -
4	Rye	0,46 / -	4	Rye	0,46 / -
4	Milk and milk	0,0234 / -	4	Milk and milk	0,0234 / -
2	Bovine: Kidney	0,3276 / -	2	Bovine: Kidney	0,3276 / -
1	Bovine: Meat	0,0702 / -	1	Bovine: Meat	0,0702 / -
1	Bovine: Liver	0,1014 / -	1	Bovine: Liver	0,1014 / -
1	Sheep: Meat	0,07488 / -	1	Sheep: Meat	0,07488 / -
1	Barley	0,38 / -	1	Barley	0,38 / -
1	Milk and milk	0,0234 / -	1	Milk and milk	0,0234 / -
1	Birds' eggs	0,039 / -	1	Birds' eggs	0,039 / -
1	Poultry: Meat	0,039 / -	1	Poultry: Meat	0,039 / -
1	Horse: Meat	0,0702 / -	1	Horse: Meat	0,0702 / -
1	Other farm animals:	0,0702 / -			
1	Bovine: Edible offal	0,05 / -			
No of critical MRLs (IESTI 1)			---		

No of commodities for which ARfD/ADI is exceeded:		---
		*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

Acute risk assessment / adults / general population - refined calculations

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
5	Oats	2,42 / -	5	Oats	2,42 / -
4	Wheat	0,37 / -	4	Wheat	0,37 / -
4	Barley	0,38 / -	4	Barley	0,38 / -
3	Rye	0,46 / -	3	Rye	0,46 / -
3	Pears	0,1 / -	2	Pears	0,1 / -
1	Bovine: Kidney	0,3276 / -	1	Bovine: Kidney	0,3276 / -
1	Poultry: Meat	0,039 / -	1	Poultry: Meat	0,039 / -
1	Bovine: Meat	0,0702 / -	1	Bovine: Meat	0,0702 / -
1	Milk and milk products: Cattle	0,0234 / -	1	Milk and milk products: Cattle	0,0234 / -
1	Sheep: Meat	0,07488 / -	1	Sheep: Meat	0,07488 / -
0	Bovine: Liver	0,1014 / -	0	Bovine: Liver	0,1014 / -
0	Swine: Meat	0,039 / -	0	Swine: Meat	0,039 / -
0	Other farm animals:	0,0702 / -	0	Other farm animals: Meat	0,0702 / -
0	Poultry: Liver	0,039 / -	0	Poultry: Liver	0,039 / -
0	Milk and milk	0,0234 / -	0	Milk and milk products: Goat	0,0234 / -
			0	Bovine: Edible offal	0,05 / -
			0	Birds' eggs	0,039 / -
No of critical MRLs (IESTI 2)			---		

No of commodities for which ARfD/ADI is exceeded:		---
		*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Chlormequat IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 31/10/2013 11:30))

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
100000	1. FRUIT FRESH OR FROZEN NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,1
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (Sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberries and other Rubus hybrids)	0,05*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries)	0,05*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other Ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (Arbutus berry)	0,05*
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	0,05*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sallowthorn, hawthorn, serviceberries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0,05*
161020	Figs	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilean cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,05*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,05*
213050	Jerusalem artichokes (Crosne)	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,05*
213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Other bulb onions, silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0,05*
231040	Okra (lady's fingers)	0,05*
231990	Others	0,05*
232000	(b) Cucurbits — edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash, marrow (late variety))	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn (Baby corn)	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choi sum, Peking cabbage/pe-tsai)	0,05*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,05*
243990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian corn salad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	0,05*
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp, including turnip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajer leaves, bitterblad/bitawiri)	0,05*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glassworth, agretti (Salsola soda))	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,05*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
	spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cisely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0,05*
256040	Parsley (leaves of root parsley)	0,05*
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0,05*
256060	Rosemary	0,05*
256070	Thyme (Marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0,05*
256090	Bay leaves (laurel) (Lemon grass)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0,05*
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons (Borago officinalis stems)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes (Banana flower)	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	10
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	7
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	7
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,1*
401110	Safflower	0,1*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0,1*
401130	Gold of pleasure	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	2
500020	Buckwheat (Amaranthus, quinoa)	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,05*
500050	Oats	5
500060	Rice (Indian/wild rice (Zizania aquatica))	0,05*
500070	Rye	2
500080	Sorghum	0,05*
500090	Wheat (Spelt, triticale)	2
500990	Others (Canary grass seeds (Phalaris canariensis))	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves (Ginkgo leaves)	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoabeans (fermented or dried)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried)	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Sichuan pepper (Anise pepper, Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black, green and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Tissue	
1011000	(a) Swine	0,05*
1011010	Muscle	0,05*
1011020	Fat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	
1012010	Muscle	0,05*
1012020	Fat	0,05*
1012030	Liver	0,1*
1012040	Kidney	0,2*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Muscle	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Muscle	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Muscle	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Muscle	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Chlormequat
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	0,05*
1017010	Muscle	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Bird eggs	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products (Wild game)	0,05*

(*) Indicates lower limit of analytical determination

Appendix D. Results of official controls of the Netherlands of the years 2010, 2011 and 2012

Origin of the sample	Date	Sample number	Product indication	Residue of chlormequat (mg/kg)*
Argentinie	2011	66819655	peren	
		66819663	peren	
		76170215	peren	
		76170592	peren Packham	
		76500193	peren	
		77637516	pears ORGANIC, BEURRE BOSC	
	2012	65355698	Rosauer Pears	
		76456062	handpeer anjou biologisch	
		76495386	peren	
Belgie	2011	69180787	BFV peren	
Chili	2011	66819698	Peren Nashi	
		66829499	peren, doyenne du comice	
		76500053	peren	
	2012	76413096	peer	
		76480958	peren	
		76481881	pears/peras packam's	
		76686432	peren	
China	2012	69084885	peer	0,014
		76189811	Ya pear	
		76219834	peren	
		76342261	peer, Golden peer, Hua Guang pear	
		76699712	emerald green stone pear	0,056
		76700494	Peren Golden Pear	0,034
Frankrijk	2011	69146759	peer alexandrine	
		76507805	Peren Guyot	
	2012	76407967	ets noel armiel cour de la gare/peer	
Italie	2010	68629071	ABATE	0
Nederland	2010	54299869	Peren Conference.	0,013
		54613369	handperen. conference	0,011
		66754278	peer conference	
		66878198	Peren Conference	0,091
		68779812	conference	
		68801788	peren	
		77441417	zoete kleine peertjes-conference	0
		77596453	handpeer	
	2011	69128793	conference	0,009
		69168272	peren	
		69395546	peer gieser wildeman	
		69412408	peen	
		69526519	conference peer	
		69679021	conference(peren)	
		76132658	conference peren	0,016
		76171068	triomphe de vienne peren	
		76176612	peer	0,009
		76180067	conference peren	0,053
		76180997	conference peer	0,012
		76212562	peren	0,012
		76248052	Peren, Conferance klasse II	0,024

Origin of the sample	Date	Sample number	Product indication	Residue of chlormequat (mg/kg)*
		76331871	peer conference	
		76400601	stoof peer gieser wildeman	
		76402477	peer clapps	0,011
		76500355	Peren Conference	0,013
		76503338	Peren Clapps	0,013
		76510172	peer Triompe de Vienne	0,017
		77944419	conference peren	
	2012	69131573	conference, 60-70 mm	0,014
		69131948	conference	0,017
		69132626	Bio ,handpeer conference	
		69318762	doy du comice	0,025
		69478719	conference	0,12
		69610048	conference	0,015
		69720501	conference peren	
		69857043	Conference zoete handpeer	
		69971822	doyenne du commice	
		69971849	doyenne du commice	
		69971865	Giesser wildermann, stoofpeer	
		69971873	St Remy, peer	
		69971881	conference, peer	
		76189463	conference	
		76189579	conference	
		76189595	gieser wildeman peer	
		76189781	comice peren	
		76190569	conference peer	
		76368546	peer Bonnelouise	
		76368694	peer conference	0,012
		76368708	peer comice	0,017
		76422192	Peren Conference	
		76438951	conference peren	0,01
		76486158	conference peer	
		76487936	conference peren	
		76518882	conference peren	
		76529965	gestoofde gieser wildeman	
		76635064	doy. du. comice peer	
		76650888	peer	
Onbekend	2012	69575536	Peren, conference	
Turkije	2012	76219826	peren	
Zuid Afrika	2011	66819671	Peren William's bon	
		66822125	Peren (Doyenne du Comice)	
		69392466	peer	
		69393004	peer	
		76500207	peren	
	2012	76396116	peer	
		76495637	peer	
		76665729	Peer Forelle	

* Empty cells refer to results below the LOQ/LOD

Appendix E. Official controls of Belgium of 2010, 201 and 2012

Chlorméquat 2010-2011-2012

2010

MON Numéro	MAT N4 Descr	MNN Date	MNN Origine - Concat	PAR Alpha Description	RES Résultat	RES Unité Résultat
1077100004	Poires	28/01/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100005	Poires	28/01/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100006	Poires	28/01/2010	Belgique	Chlorméquat	0,12	mg/kg
1077100007	Poires	23/02/2010	Belgique	Chlorméquat	0,099	mg/kg
1077100008	Poires	23/02/2010	Belgique	Chlorméquat	0,011	mg/kg
1077100009	Poires	23/02/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100010	Poires	23/02/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100014	Poires	17/03/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100015	Poires	17/03/2010	Belgique	Chlorméquat	0,029	mg/kg
1077100016	Poires	17/03/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100021	Poires	26/04/2010	Belgique	Chlorméquat	<LOQ	mg/kg
1077100087	Poires	3/11/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100088	Poires	3/11/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100089	Poires	8/11/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100090	Poires	8/11/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100094	Poires	17/11/2010	Belgique	Chlorméquat	0,027	mg/kg
1077100096	Poires	23/11/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1077100099	Poires	25/11/2010	Belgique	Chlorméquat	<LOQ	mg/kg
1213100005	Poires	18/01/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1340100071	Poires	26/05/2010	Belgique	Chlorméquat	0,017	mg/kg
1406100032	Poires	2/03/2010	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
1406100033	Poires	3/03/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100034	Poires	3/03/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100035	Poires	4/03/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100036	Poires	4/03/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100049	Poires	25/03/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100106	Poires	1/06/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100107	Poires	1/06/2010	Argentine*	Chlorméquat	< LOQ	mg/kg
1406100108	Poires	1/06/2010	Argentine*	Chlorméquat	< LOQ	mg/kg

1406100109	Poires	1/06/2010	Nouvelle-Zélande*	Chlorméquat	< LOQ	mg/kg
1406100110	Poires	1/06/2010	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
1406100111	Poires	1/06/2010	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
1584100025	Poires	13/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1584100026	Poires	13/09/2010	Belgique	Chlorméquat	0,031	mg/kg
1584100027	Poires	20/09/2010	Belgique	Chlorméquat	0,011	mg/kg
1584100028	Poires	20/09/2010	Belgique	Chlorméquat	0,023	mg/kg
1584100029	Poires	20/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
1584100030	Poires	20/09/2010	Belgique	Chlorméquat	0,016	mg/kg
1584100031	Poires	20/09/2010	Belgique	Chlorméquat	0,054	mg/kg
1584100032	Poires	20/09/2010	Belgique	Chlorméquat	0,019	mg/kg
1584100033	Poires	20/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2094100039	Poires	19/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2119100224	Poires	12/10/2010	Belgique	Chlorméquat	0,011	mg/kg
2119100241	Poires	19/10/2010	Belgique	Chlorméquat	0,028	mg/kg
2146100153	Poires	7/09/2010	Belgique	Chlorméquat	0,012	mg/kg
2146100154	Poires	7/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2297100055	Poires	26/04/2010	Afrique du Sud*	Chlorméquat	<LOQ	mg/kg
2324100042	Poires	26/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2359100115	Poires	28/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2359100134	Poires	13/10/2010	Belgique	Chlorméquat	0,09	mg/kg
2380100087	Poires	11/06/2010	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
2429100007	Poires	16/02/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2429100008	Poires	22/02/2010	Belgique	Chlorméquat	0,025	mg/kg
2429100064	Poires	29/09/2010	Belgique	Chlorméquat	0,021	mg/kg
2429100067	Poires	11/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2429100069	Poires	25/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2524100091	Poires	13/07/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2524100122	Poires	8/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2563100006	Poires	29/09/2010	Belgique	Chlorméquat	0,028	mg/kg
2563100007	Poires	29/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2563100008	Poires	29/09/2010	Belgique	Chlorméquat	<LOQ	mg/kg
2563100009	Poires	29/09/2010	Belgique	Chlorméquat	<LOQ	mg/kg
2563100010	Poires	29/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg

2563100011	Poires	14/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2563100012	Poires	14/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2563100013	Poires	14/10/2010	Belgique	Chlorméquat	< loq	mg/kg
2563100014	Poires	14/10/2010	Belgique	Chlorméquat	< LOQ	mg/kg
2563100509	Poires	1/09/2010		Chlorméquat	< LOQ	mg/kg
2563100510	Poires	1/09/2010		Chlorméquat	< LOQ	mg/kg
2563100511	Poires	1/09/2010		Chlorméquat	< LOQ	mg/kg
2563100512	Poires	1/09/2010		Chlorméquat	< LOQ	mg/kg
2563100513	Poires	7/09/2010		Chlorméquat	< LOQ	mg/kg
2563100514	Poires	7/09/2010		Chlorméquat	0,052	mg/kg
2563100515	Poires	7/09/2010		Chlorméquat	0,011	mg/kg
2563100516	Poires	7/09/2010		Chlorméquat	0,077	mg/kg
2563100517	Poires	7/09/2010		Chlorméquat	< LOQ	mg/kg
2563100518	Poires	7/09/2010		Chlorméquat	0,068	mg/kg
2563100519	Poires	7/09/2010		Chlorméquat	< LOQ	mg/kg
2563100520	Poires	7/09/2010		Chlorméquat	0,038	mg/kg
2563100521	Poires	8/09/2010		Chlorméquat	< LOQ	mg/kg
2563100522	Poires	8/09/2010		Chlorméquat	< LOQ	mg/kg
2563100523	Poires	13/09/2010		Chlorméquat	0,027	mg/kg
2563100524	Poires	13/09/2010		Chlorméquat	< LOQ	mg/kg
2563100525	Poires	30/09/2010	Belgique	Chlorméquat	0,029	mg/kg
2563100526	Poires	30/09/2010	Belgique	Chlorméquat	0,010	mg/kg
2563100527	Poires	30/09/2010	Belgique	Chlorméquat	0,017	mg/kg
3013100093	Poires	17/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3013100094	Poires	17/09/2010	Belgique	Chlorméquat	0,023	mg/kg
3013100103	Poires	4/10/2010	Belgique	Chlorméquat	0,025	mg/kg
3091100096	Poires	17/08/2010	Espagne*	Chlorméquat	< LOQ	mg/kg
3259100038	Poires	1/03/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3259100145	Poires	6/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3259100152	Poires	24/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3259100170	Poires	15/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3259100171	Poires	15/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3259100190	Poires	1/12/2010	Belgique	Chlorméquat	< LOQ	mg/kg
3260100076	Poires	17/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg

3295100081	Poires	10/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
4076100005	Poires	20/09/2010	Belgique	Chlorméquat	0,012	mg/kg
4076100007	Poires	27/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
4076100008	Poires	29/09/2010	Belgique	Chlorméquat	< LOQ	mg/kg
101						
2011						
MON Numéro	**MAT N4 Descr**	**MNN Date**	**MNN Origine - Concat**	**PAR Alpha Description**	**RES Résultat**	**RES Unité Résultat**
1050110075	Poires	9/05/2011	Chili*	Chlorméquat	< LOQ	mg/kg
1050110076	Poires	9/05/2011	Nouvelle-Zélande*	Chlorméquat	< LOQ	mg/kg
1050110077	Poires	11/05/2011	Chili*	Chlorméquat	< LOQ	mg/kg
1050110121	Poires	26/07/2011	France*	Chlorméquat	< LOQ	mg/kg
1075110008	Poires	26/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1075110021	Poires	24/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1075110028	Poires	21/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1075110034	Poires	5/12/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110004	Poires	16/02/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110005	Poires	16/02/2011	Belgique	Chlorméquat	0,012	mg/kg
1077110006	Poires	24/02/2011	Belgique	Chlorméquat	0,013	mg/kg
1077110019	Poires	11/05/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110089	Poires	14/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110090	Poires	29/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110093	Poires	30/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110094	Poires	30/09/2011	Belgique	Chlorméquat	0,017	mg/kg
1077110099	Poires	3/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110100	Poires	3/11/2011	Pays-Bas	Chlorméquat	< LOQ	mg/kg
1077110104	Poires	8/11/2011	Belgique	Chlorméquat	0,098	mg/kg
1077110108	Poires	22/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110109	Poires	22/11/2011	Belgique	Chlorméquat	0,019	mg/kg
1077110114	Poires	29/11/2011	Belgique	Chlorméquat	0,063	mg/kg
1077110117	Poires	6/12/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1077110118	Poires	13/12/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1213110001	Poires	11/01/2011	Belgique	Chlorméquat	0,014	mg/kg
1213110081	Poires	27/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1213110086	Poires	17/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg

1213110088	Poires	17/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1213110089	Poires	17/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1213110094	Poires	18/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1406110035	Poires	3/03/2011	Argentine*	Chlorméquat	< LOQ	mg/kg
1406110069	Poires	16/05/2011	Chili*	Chlorméquat	< LOQ	mg/kg
1406110080	Poires	6/06/2011	Nouvelle-Zélande*	Chlorméquat	< LOQ	mg/kg
1406110081	Poires	6/06/2011	Nouvelle-Zélande*	Chlorméquat	< LOQ	mg/kg
1444110038	Poires	21/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110039	Poires	21/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110045	Poires	25/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110046	Poires	25/10/2011	Belgique	Chlorméquat	0,045	mg/kg
1444110047	Poires	27/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110049	Poires	28/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110055	Poires	24/11/2011	Belgique	Chlorméquat	0,019	mg/kg
1444110056	Poires	24/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110057	Poires	24/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
1444110059	Poires	15/12/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2297110017	Poires	24/01/2011	Belgique	Chlorméquat	0,02	mg/kg
2297110118	Poires	14/04/2011	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
2297110150	Poires	15/06/2011	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
2297110324	Poires	26/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2324110011	Poires	25/01/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2324110012	Poires	25/01/2011	Belgique	Chlorméquat	0,012	mg/kg
2324110079	Poires	8/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2324110080	Poires	8/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2324110081	Poires	8/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2359110188	Poires	7/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2429110033	Poires	4/04/2011	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
2429110034	Poires	6/04/2011	Argentine*	Chlorméquat	< LOQ	mg/kg
2429110037	Poires	19/04/2011	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
2488110035	Poires	31/03/2011	Argentine*	Chlorméquat	< LOQ	mg/kg
2576110062	Poires	6/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2576110077	Poires	22/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2576110085	Poires	19/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg

2576110096	Poires	25/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2597110060	Poires	23/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2598110168	Poires	5/10/2011	Belgique	Chlorméquat	0,039	mg/kg
2599110056	Poires	24/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
2600110026	Poires	27/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
3013110014	Poires	22/02/2011	Pays-Bas	Chlorméquat	0,025	mg/kg
3259110013	Poires	25/01/2011	Belgique	Chlorméquat	< LOQ	mg/kg
3259110152	Poires	22/09/2011	Belgique	Chlorméquat	< LOQ	mg/kg
3259110157	Poires	14/10/2011	Belgique	Chlorméquat	< LOQ	mg/kg
3295110079	Poires	10/11/2011	Belgique	Chlorméquat	< LOQ	mg/kg
4035110001	Poires	2/02/2011	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
4040110048	Poires	4/04/2011	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
73						
2012						
MON Numéro	**MAT N4 Descr**	**MNN Date**	**MNN Origine - Concat**	**PAR Alpha Description**	**RES Résultat**	**RES Unité Résultat**
1041120131	Poires	2/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1050120031	Poires	23/01/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1050120038	Poires	25/01/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1050120088	Poires	2/05/2012	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
1050120204	Poires	17/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1075120001	Poires	16/01/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120013	Poires	21/02/2012	Belgique	Chlorméquat	0,037	mg/kg
1077120014	Poires	21/02/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120158	Poires	18/09/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120159	Poires	19/09/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120178	Poires	16/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120179	Poires	16/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120180	Poires	16/10/2012	Belgique	Chlorméquat	0,019	mg/kg
1077120189	Poires	30/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1077120194	Poires	21/11/2012	Belgique	Chlorméquat	0,045	mg/kg
1077120198	Poires	21/11/2012	Belgique	Chlorméquat	0,098	mg/kg
1213120001	Poires	13/01/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1213120020	Poires	14/02/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1213120031	Poires	3/04/2012	Belgique	Chlorméquat	0,014	mg/kg

1213120053	Poires	11/06/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1213120090	Poires	20/08/2012	Belgique	Chlorméquat	0,02	mg/kg
1213120130	Poires	1/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1213120131	Poires	1/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1213120132	Poires	8/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1213120152	Poires	5/11/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1406120058	Poires	24/05/2012	Nouvelle-Zélande*	Chlorméquat	< LOQ	mg/kg
1406120059	Poires	24/05/2012	Argentine*	Chlorméquat	< LOQ	mg/kg
1444120003	Poires	7/02/2012	Belgique	Chlorméquat	0,022	mg/kg
1444120004	Poires	7/02/2012	Belgique	Chlorméquat	0,023	mg/kg
1444120006	Poires	13/02/2012	Belgique	Chlorméquat	0,029	mg/kg
1444120008	Poires	5/03/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1444120009	Poires	5/03/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1444120127	Poires	26/09/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1444120169	Poires	21/11/2012	Belgique	Chlorméquat	< LOQ	mg/kg
1444120171	Poires	21/11/2012	Belgique	Chlorméquat	< LOQ	mg/kg
2094120083	Poires	24/09/2012	Belgique	Chlorméquat	< LOQ	mg/kg
2094120093	Poires	1/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
2317120035	Poires	24/02/2012	Belgique	Chlorméquat	< LOQ	mg/kg
2317120075	Poires	19/04/2012	Belgique	Chlorméquat	0,018	mg/kg
2317120119	Poires	28/06/2012	Chili*	Chlorméquat	< LOQ	mg/kg
2429120018	Poires	28/02/2012	Belgique	Chlorméquat	< LOQ	mg/kg
2429120039	Poires	14/05/2012	Afrique du Sud*	Chlorméquat	< LOQ	mg/kg
2429120090	Poires	24/09/2012	Belgique	Chlorméquat	0,046	mg/kg
2491120092	Poires	23/10/2012	Belgique	Chlorméquat	< LOQ	mg/kg
2597120157	Poires	20/11/2012	Belgique	Chlorméquat	0,034	mg/kg
3013120194	Poires	6/11/2012	Belgique	Chlorméquat	< LOQ	mg/kg
3091120149	Poires	18/09/2012	Belgique	Chlorméquat	0,023	mg/kg
3122120001	Poires	3/02/2012	Belgique	Chlorméquat	< LOQ	mg/kg
3259120047	Poires	24/02/2012	Belgique	Chlorméquat	< LOQ	mg/kg
3259120143	Poires	22/08/2012	Belgique	Chlorméquat	< LOQ	mg/kg
3259120176	Poires	7/11/2012	Belgique	Chlorméquat	0,078	mg/kg
3259120196	Poires	21/11/2012	Belgique	Chlorméquat	0,012	mg/kg
52						

*Data not relevant and not considered in the framework of the current application.

Appendix F. Control results from the Dutch Fruit growers association

MRL	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.5	0.5	3	3	3
Grower No.	**2012**	**2011**	**2010**	**2009**	**2008**	**2007**	**2006**	**2005**	**2004**	**2003***	**2002***	**2001***	**2000***	**1999***	**1998***
1	-	0.06	0.02	**0.11**	0.01	0.075	0.15	0.14	0.17	0.10	0.36	0.25	0.38	1.1	**3.5**
2	0.02	<0.01	0.02	0.04	0.05	0.012	0.04	0.02	0.05	0.07	0.06	0.21		< 0.50	4/<1
3	0.02	0.03	0.02	0.09	0.02	0.078	0.03	<0.01	<0.01	<0.01	0.14	0.20	0.17	1.6	1.5
4	0.05	0.02	0.01	0.08	0.04	0.01	0.04	0.06	0.09	0.09	0.19	0.077	0.26	< 0.50	**4.3/6.6/3.2**
5	0.06	0.02	0.04	0.01	0.05	0.052	0.04	0.09	0.08	0.16	0.20	0.24	0.50	0.51	**5.6/4.6/2.6**
6	<0.01	0.04	0.03	0.04	0.11	0.023	0.03	0.01	0.04	0.03	0.19	0.25	0.27	0.58	2.6
7	-	-	-	-	-	-	-	-	-	-	-	-	0.18	0.59	1.2
8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.02	0.02	<0.01	0.06	0.03	-	0.22	0.55	**3.1**
9	0.04	0.03	<0.01	0.01	0.01	0.016	0.02	0.04	<0.01	0.05	0.01	0.18	0.15	0.59	**3.6/3.1/2.1**
10	0.01	<0.01	0.01	0.03	0.03	<0.01	0.02	0.09	0.03	0.04	0.04	-	0.17	0.93	2.2
11	0.10	-	0.05	0.03	<0.01	0.062	<0.01	<0.01	<0.01	<0.01	0.03				
12	-	-	-	-	0.02	0.068	0.16	0.09	0.21	-	0.57				
13	-	-	-	<0.01	<0.01	0.05	0.02	0.06	<0.01	0.06	0.07				
14	-	-	-	-	-	-	-	-	<0.01	0.02	0.07				
15	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01				
16	-	<0.01	0.06	0.02	0.06	<0.01	<0.01	0.03	0.04	0.05	0.09				
17	-	-	-	-	-	-	-	0.135	0.05	0.15	0.20				
18	-	-	-	-	-	-	0.02	0.05	0.06	<0.01	0.17				
19	-	-	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.06				
20	-	-	-	-	-	0.039	0.03	0.02	<0.01	0.12	0.13				
21	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.02	0.11	<0.01	0.03	0.24				
22	-	-	-	-	-	-	<0.01	<0.01	<0.01	<0.01	<0.01				
23	-	-	-	-	-	<0.01	<0.01	<0.01	<0.01	<0.01	0.03				
24	0.03	<0.01	0.02	0.01	0.03	0.031	0.02	0.04	0.05	0.24	0.52				
25	-	-	0.06	<0.01	0.04	<0.01	0.03	0.05	0.05	0.04	0.21				
26	-	-	-	-	-	-	-	-	0.10	0.17	0.31				
27	0.04	0.09	0.03	0.06	0.09	0.035	0.03	0.06	0.03	0.10	0.23				
28	0.06	0.02	0.04	0.05	0.12	0.015	0.03	0.10	0.03	0.08	0.12				
29	0.09	0.02	0.04	0.04	<0.01	<0.01	<0.01	<0.01	<0.01	0.02	0.14				
30	-	-	-	-	<0.01	<0.01	<0.01	0.01	0.01	<0.01	0.05				
31	0.04	0.02	<0.01	0.01	0.02	0.011	0.02	0.03	<0.01	0.02	0.03				
32	0.02	0.03	0.03	0.02	0.06	0.052	0.03	0.05	0.05	0.09	0.01				
33	<0.01	<0.01	0.03	<0.01	<0.01	<0.01	0.02	0.02	<0.01	0.03	0.09	0.43	0.29	0.69	1.8
34	-	0.03	0.02	0.02	0.03	0.069	0.08	0.07	0.06	0.05	0.12	0.11	0.25	0.51	**3.8/5.0/6.2/3.1**
35	-	-	-	-	-	-	-	-	-	-	0.05	**2.00**	0.92	**4.15**	
36	-	-	-	-	-	-	-	-	-	-	-	-	0.38		
37	-	-	-	-	-	-	-	-	-	-	-	-	0.23	1.10	**5.4**
38	-	-	-	-	-	-	-	-	-	-	-	-	0.29	1.80	**5.7/5.0**
39	-	-	-	-	-	-	-	-	-	-	0.02	-	0.13	0.90	**5.7/4.7/3.8/1.0**
40	-	<0.01	0.02	<0.01	0.02	0.017	0.01	0.01	0.03	0.04	0.22	0.19	0.06		<1
41	0.06	0.03	0.05	0.02	0.01	<0.01	0.01	0.02	<0.01	0.01	0.01	0.10	0.11	1.10	**6.5/6.0**

42	-	-	-	-	-	-	-	-	-	-	-	-	0.31	2.40	
43	0.02	<0.01	<0.01	<0.01	<0.01	0.02	0.08	0.05	0.10	0.07	0.25	0.084	0.26	0.67	<1
44	-	-	-	-	-	-	0.02	0.06	0.03	0.03	0.08	0.25	0.32	0.73	<1
45	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	< 0.01	<0.01	<0.01	-	<0.05	0.10	< 0.50	11
46	-	0.06	0.08	**0.16**	0.11	0.140	0.07	0.25	0.24	**0.31**	0.28	0.50	0.73	1.30	**11/3.3**
47	-	-	-	0.02	0.02	0.026	0.12	0.03	0.03	0.07	0.05	0.17	0.35	2.30	9.5/1.0
48	-	-	-	-	-	-	-	-	-	-	-	-	<0.05	< 0.50	
49	-	-	-	-	-	-	-	-	-	-	-	-	0.09		1.4
50	<0.01	<0.01	<0.01	0.02	<0.01	<0.01	<0.01	< 0.01	0.01	0.02	0.05	<0.05	0.07	< 0.50	
51	0.07	0.10	0.04	0.05	0.03	0.035	0.09	0.10	0.07	0.07	0.17	<0.05	0.72	1.10	6.9/2.6
52	-	-	-	-	-	-	-	-	-	-	-	-	<0.05	0.79	
53	-	-	-	-	-	-	-	-	-	-	-	-	0.17	1.30	1.7
54	<0.01	<0.01	0.03	<0.01	0.01	0.021	0.03	0.02	0.03	0.03	0.08	<0.05	-	-	<1
55	-	-	-	-	-	-	-	0.03	0.02	<0.01	0.06	0.20	-	0.75	-
56	<0.01	<0.01	<0.01	<0.01	0.02	0.034	0.01	0.05	0.06	0.02	0.09	0.053	0.13	< 0.50	-
57	-	-	-	-	-	-	-	0.03	<0.01	0.08	0.08	0.08	-	-	-
58	-	0.04	0.02	0.04	0.02	0.059	0.07	0.05	0.01	0.06	0.22	0.22	0.15	0.50	**5.4**
59	0.01	0.05	<0.01	<0.01	<0.01	0.027	0.01	<0.01	0.11	0.07	0.21	0.21	0.20	-	**3.6**
60	0.06	0.02	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	<0.01	0.18	0.29	0.18	< 0.50	3
61	0.03	<0.01	<0.01	0.07	0.12	<0.01	0.01	<0.01	<0.01	<0.01	0.05	<0.05	0.23	0.63	<1
62	0.04	0.01	<0.01	0.03	<0.01	<0.01	<0.01	<0.01	<0.01	0.07	0.50	<0.05	0.18	0.54	**4.3**
63	0.02	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	0.01	<0.01	<0.01	<0.01	<0.05	0.076	< 0.50	2.8
64	0.04	<0.01	<0.01	<0.01	<0.01	<0.01	**0.22**	0.04	0.07	0.07	0.27	<0.05	0.20	0.64	**6.4/2.8**
65	0.01	<0.01	<0.01	<0.01	<0.01	0.02	0.01	0.02	0.19	0.03	0.11	0.16	0.29	< 0.50	**3.8**
66	0.10	0.03	0.01	0.05	0.04	<0.01	0.02	0.01	<0.01	0.04	0.08	0.22	0.79	< 0.50	2.2
67	-	-	0.04	**0.11**	0.03	<0.01	0.10	0.06	<0.01	0.18	0.03	0.19	0.34	1.60	10
68	0.02	0.05	0.09	**0.14**	0.14	0.180	**0.21**	0.27	<0.01	0.06	0.09	0.098	-	**3.30**	1.3
69	<0.01	<0.01	<0.01	<0.01	0.02	<0.01	<0.01	0.01	<0.01	0.07	0.08	0.18	-	0.97	2.4
70	-	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.03	<0.01	0.07	0.061	-	< 0.50	1.2
71	-	-	-	0.04	0.02	0.024	0.04	0.07	<0.01	0.05	<0.01	<0.05	0.075	< 0.50	**3.3**
72	0.09	<0.01	0.03	0.07	0.17	0.067	0.16	0.03	0.08	0.09	0.16	0.42	-	1.20	2.1
73	<0.01	0.05	<0.01	<0.01	<0.01	0.011	0.02	0.02	0.05	0.06	0.11	0.13	-	-	**3.3**
74	-	-	-	0.04	0.07	0.040	0.10	0.07	0.09	0.06	0.34	0.18	-	0.68	**3.1**
75	-	<0.01	0.04	0.01	<0.01	<0.01	0.13	0.08	<0.01	<0.01	0.04	0.28	-	-	**13**
76	<0.01	<0.01	<0.01	<0.01	0.03	<0.01	0.02	0.02	0.04	0.06	0.06	0.12	-	-	1.6
77	-	-	-	-	-	-	-	-	0.11	**0.32**	0.36	0.28	0.45	0.94	**6.2**
78	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.04	<0.01	0.19	0.26	0.32	< 0.50	11
79	-	<0.01	0.07	0.10	0.08	<0.01	<0.01	0.06	0.02	0.13	0.22	0.31	0.25	0.93	2.9
80	0.02	<0.01	<0.01	0.02	0.02	0.023	0.02	0.02	0.02	0.05	0.09	0.11	0.42	0.87	-
81	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.02	<0.01	0.08	0.054	0.086	-	1.1
82	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.02	0.02	0.06	0.11	0.095	0.15	1.00	**4.1**
83	0.09	0.03	0.05	0.02	0.07	0.089	0.11	0.03	0.03	0.3	0.07	0.052	0.16	0.66	**5.5**
84	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.13	0.09	0.13	-	-	1.7/4.4
85	-	-	0.02	0.01	0.03	0.015	0.03	0.04	0.02	0.04	0.13	0.13	<0.05	-	1.9
86											0.12	0.23			

87											0.15	0.25			
88									0.02	0.06	0.17	0.05			
89									<0.01	<0.01	0.08	0.30			
90										0.16	0.20	<0.05			
91									0.06	0.02	0.05	0.06			
92											0.02	<0.05			
93									<0.01	0.09	0.02	<0.05			
94									<0.01	0.01	0.09	0.05			
95											0.06	0.32			
96									<0.01	<0.01	0.01	0.07			
97									<0.01	0.1	0.09	0.06			
98									<0.01	0.01	0.03	<0.05			
99											0.03	0.07			
100									<0.01	0.04	0.18	<0.05			
101									0.08		0.18				
102									<0.01	<0.01					
Total	**44**	**52**	**57**	**61**	**63**	**65**	**68**	**71**	**85**	**84**	**91**	**66**	**50**	**51**	**76**
Mean	**0.033**	**0.023**	**0.024**	**0.032**	**0.034**	**0.029**	**0.041**	**0.045**	**0.039**	**0.063**	**0.128**	**0.181**	**0.258**	**0.961**	**3.89**

*Data not considered in the framework of the current application.

Notes to the table above (Netherlands, 2013):

The data indicate the changes in chlormequat chloride residue levels from 1998 onwards. All samples were taken from Conference pears grown in the Netherlands. Each number corresponds to a grower. Each year 1 sample per grower was taken from the same orchard, except in 1998 and when in doubt. 3 growers used chlormequat chloride up to 2000; the last year in which chlormequat chloride was applied. MRL is the abbreviation for Maximum Residue Limit. The unit of measure of the data is mg chlormequat chloride per kg pear. Between 2001 and 2004 samples from private sales and marketing organisations were included in this table. The decrease in the number of growers is due to the orchards being cleared and growers leaving the sales and marketing organisations. Where the transitional standard is exceeded, the figures are shown in bold. Values of 0 are considered as <0.01, <0.05 or < 0.50, depending on the accuracy of the measurements. For calculating the averages, the values <0.01 were are set at 0.01 ,<0.05 at 0.05, and <0.5 at 0.5. The analyses were conducted by certified laboratories.

Appendix G. Control results from Belgium growers organisation (Verbond van Belgische Tuinbouwcoöperaties (VBT))

Staal nemer	Staalnr	Product	Herkomst	Actieve stof	Resultaat	Eenheid	Labo	Datum staalname	Datum analyserapport
PO		peer	B	chloormequat	0,009	ppm	Lab001	7-12-2011	
PO		peer	B	chloormequat	0,009	ppm	Lab001	7-12-2011	
PO		peer	B	chloormequat	0,009	ppm	Lab001	7-12-2011	
PO		peer	B	chloormequat	0,009	ppm	Lab001	7-12-2011	
PO	1	peer	B	chloormequat	0,012	ppm	Lab001	8-11-2010	12-11-2010
PO	2	peer	B	chloormequat	0,014	ppm	Lab001	9-11-2010	16-11-2010
PO	3	peer	B	chloormequat	0,015	ppm	Lab001	21-4-2011	2-5-2011
PO	4	peer	B	chloormequat	0,02	ppm	Lab001	4-3-2010	
PO	5	peer	B	chloormequat	0,021	ppm	Lab001	7-3-2012	13-3-2012
PO	6	peer	B	chloormequat	0,029	ppm	Lab001	26-5-2010	28-5-2010
PO	7	peer	B	chloormequat	0,029	ppm	Lab001	9-11-2010	16-11-2010
PO	8	peer	B	chloormequat	0,03	ppm	Lab001	2-3-2010	
PO	9	peer	B	chloormequat	0,032	ppm	Lab001	29-11-2012	4-12-2012
PO	10	peer	B	chloormequat	0,06	ppm	Lab002	6-9-2010	8-9-2010
PO	11	peer	B	chloormequat	0,069	ppm	Lab001	27-10-2010	5-11-2010
PO	12	peer	B	chloormequat	0,08	ppm	Lab001		13-10-2010
PO	13	peer	B	chloormequat	0,12	ppm	Lab001	7-12-2011	

Overzicht	Stalen	NA <0,01	0,010-0,049	0,050-0,099	≥ 0,1
2010	32	23	6	3	0
2011	16	14	1	0	1
2012	13	11	2	0	0
2010-2012	61	48	9	3	1
	100 %	79 %	15 %	5 %	2 %

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DK	Denmark
DM	dry matter
DT_{90}	period required for 90 % dissipation
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
IE	Ireland
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre

LOQ	limit of quantification
mo	month
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
SL	soluble concentrate
TRR	total radioactive residue
WHO	World Health Organization
wk	week
yr	year